

US3552232 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:15:12

All time stamps listed in this document are displayed in GMT

US3552232

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:20:32

Generated On: 10 Jun 2021 08:15:12

Participant ID

US3552232

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

US3552232

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552232

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3552232

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3552232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	URINARY RETENTION
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	MRSA POSITIVE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	DIABETIC RETINOPATHY LEFT EYE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	LEFT LENS EROSION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	RIGHT SHOULDER DISLOCATION
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1951
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1951
Start Year (derived)	1951
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	24 JAN 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	RIGHT LOWER EXTREMITY CELLULITIS
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	DEPRESSION
Start date (dd MMM yyyy)	13 JUN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	SENSORY DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	21 JUL 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	DIVERTICULOSIS OF COLON
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	GASTRITIS
Start date (dd MMM yyyy)	10 OCT 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	H. PYLORI INFECTION
Start date (dd MMM yyyy)	12 OCT 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	13 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	28 APR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	01 NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	ADENOMATOUS COLON POLYP
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	COLONOSCOPY
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	TUBERCULOSIS EXPOSURE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	PYURIA
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Condition	CORONARY ARTERY STENT
Start date (dd MMM yyyy)	20 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:20:54

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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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:20:54

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Resides in Nursing Home or Assisted Living Facility	False
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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Height	ND - Not Done
Weight	ND - Not Done

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:12

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 ☒

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EAB) (1725)

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:12

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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: Continuing

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

SUBJECT WAS HOSPITALIZED
AND WAS UNABLE TO BE
REACHED BY PHONE

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	11:36 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:36

US3552232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:20:54

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 10 Jun 2021 08:15:12

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 10 Jun 2021 08:15:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 10 Jun 2021 08:15:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 07:16:01
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 11:02:20

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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 14:01:01
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 11:52:30

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:34:29

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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 17:02:30
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: 10 Jun 2021 08:15:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 13:19:45
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 09:00:19

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 11:42:49

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 15:23:14

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 03:02:38

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 17:18:03

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: 10 Jun 2021 08:15:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 09:17:37
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 11:08:24

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 02:33:41

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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 10:32:42
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 16:41:33

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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 MAR 2021 06:02:14
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: 10 Jun 2021 08:15:12

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 APR 2021 09:45:44
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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 12:26:25

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 10:16:19

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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 14:12:35

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: 10 Jun 2021 08:15:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

10 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

17 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

24 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

31 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

14 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

02 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

16 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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

23 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

06 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

20 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

27 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

04 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

18 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

01 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

08 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

10 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

17 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

24 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

07 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: 10 Jun 2021 08:15:12

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

14 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: 10 Jun 2021 08:15:12

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

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25 FEB 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

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04 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

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11 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

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18 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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25 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

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01 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

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Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 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: 10 Jun 2021 08:15:12

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

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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: 10 Jun 2021 08:15:12

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

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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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

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27 MAY 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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°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: 10 Jun 2021 08:15:12

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

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10 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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17 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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24 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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08 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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22 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

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29 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

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05 AUG 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

12 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

19 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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

[Patient Cloud Open Date & Time](#)

26 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: 10 Jun 2021 08:15:12

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:15:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 11:07:58

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

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

Data signed: (b) (4) 21 Feb 2021 18:20:53

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:20:39

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:26:26

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:22:31

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:57:14

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 11:00
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	180 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3552232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:57:14

Generated On: 10 Jun 2021 08:15:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	11:42 (24 HR)
Collection date and time (derived)	25 MAR 2021 11:42

US3552232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

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 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:20:34

Generated On: 10 Jun 2021 08:15:12

Date of Contact	22 JAN 2021
Time of Contact	09:07
Date and Time of Contact (derived)	22 JAN 2021 09:07
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:20:34

Generated On: 10 Jun 2021 08:15:12

Date of Visit 26 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 26 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 18:02:42

Generated On: 10 Jun 2021 08:15:12

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 27 Feb 2021 17:54:31

Generated On: 10 Jun 2021 08:15:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 JAN 2021
Day 5	Yes	29 JAN 2021
Day 7	Yes	01 FEB 2021
Day 9	Yes	03 FEB 2021
Day 14	Yes	08 FEB 2021
Day 21	Yes	15 FEB 2021
Day 28	Yes	22 FEB 2021

US3552232

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 11:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552232

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

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: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 JAN 2021

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:22:31

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:22:31

Generated On: 10 Jun 2021 08:15:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:45
Height (xxx.x)	68.5 in
Weight (xxx.x)	171 lb
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:22:31

Generated On: 10 Jun 2021 08:15:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 03:22:31

Generated On: 10 Jun 2021 08:15:12

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 FEB 2021

US3552232

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

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

Visit date (dd MMM yyyy)	26 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552232

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:31:21

Generated On: 10 Jun 2021 08:15:12

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552232

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

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

US3552232

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:39
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:57
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3552232

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 15:27 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 15:27

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 FEB 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	26 FEB 2021 14:25

US3552232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 FEB 2021
Collection time (00:00 - 23:59)	14:30
Collection Date and Time (derived)	26 FEB 2021 14:30

US3552232

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 MAR 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:57:26

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3552232

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 11:00
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	180 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 12:43
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	184 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3552232

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 MAR 2021

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 25 MAR 2021 12:13

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 13:57:13

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 APR 2021

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 OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552232

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:30:05

Generated On: 10 Jun 2021 08:15:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 APR 2021
Collection time (00:00-23:59)	12:56 (24 HR)
Collection date and time (derived)	22 APR 2021 12:56

US3552232

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:20:33

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	CRYPTOGENIC ORGANIZING PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	08 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	RESPIRATORY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	PAROXYSMAL ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	NON-ST ELEVATED MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	HYPOMAGNESIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

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.

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	ACUTE KIDNEY INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

AEID	USA-US089-2021-MRNA-1273-P30 1000002
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

AEID

Adverse event

WORSENING HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

AEID	USA-US089-2021-MRNA-1273-P30 1000008
Adverse event	CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 APR 2021
Hospital Discharge Date (dd MMM yyyy)	07 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

SUBJECT WAS AT A LOCAL
PARK WITH FAMILY OVER THE
WEEKEND; FAMILY NOTICED
ON SUNDAY THAT HE LOOKED
UNWELL. SUBJECT REPORTED
HAVING SHORTNESS OF
BREATH AND A COUGH THAT
STARTED SUNDAY, WAS
ADMITTED TO THE HOSPITAL
ON MONDAY FOR CONGESTIVE
HEART FAILURE AND ALSO
FOUND TO HAVE PNEUMONIA.
SUBJECT CURRENTLY STILL
INPATIENT; WILL SEND
MEDICAL RECORDS ONCE HE
HAS BEEN DISCHARGED.

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 (15)

Generated On: 10 Jun 2021 08:15:12

AEID	
Adverse event	PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:20:34

Generated On: 10 Jun 2021 08:15:12

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)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication NORCO
[HYDROCODONE/ACETAMINOP
HEN]

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 06 Apr 2021 15:12:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication LEVALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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

EVERY 6 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

EVERY 8 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA, RESPIRATORY
FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication CORICIDIN
[CHLORPHENIRAMINE
MALEATE/DEXTROMETHORPH
AN HYDROBROMIDE]

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 4/30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication TYLENOL #3

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 06 Apr 2021 15:12:34

Generated On: 10 Jun 2021 08:15:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 18:20:34

Generated On: 10 Jun 2021 08:15:12

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 18:20:34

Generated On: 10 Jun 2021 08:15:12

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

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 18:20:35

Generated On: 10 Jun 2021 08:15:12

Date of dosing discontinuation (dd MMM yyyy) 3 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #3

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:15:12

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 ☐

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

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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

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

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 21 Feb 2021 18:20:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 14:27:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	1

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 14:27:36

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	1
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 18:02:42

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 18:02:42

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	07/APR/2021 18:37
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-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 18:02:42

Generated On: 10 Jun 2021 08:15:12

SAEID	USA-US089-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 06:16
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: 10 Jun 2021 08:15:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'US3552232'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:35:44

US3552232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:35:45

US3552232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'SCRN'	System	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:35:46

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '70'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'YEARS'	System	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '70'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Male (M)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Aug 2020'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2020'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:35:45

US3552232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'l'	System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:15:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:53

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Metabolism and nutrition disorders, HLG: 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)	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)	12 Oct 2020 20:54:19
User entered 'TYPE 2 DIABETES' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 20:54:19
User coded data point as SOC: Metabolism and nutrition disorders, HLG: 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)	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)	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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 1992'	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '1992'	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	22 Jan 2021 16:42:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	22 Jan 2021 16:42:51
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	22 Jan 2021 16:42:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	22 Jan 2021 16:42:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2013'	Mikayla Frye (b) (4)	29 Aug 2020 18:51:58
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	22 Jan 2021 16:42:51
User entered 'Jan 2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	22 Jan 2021 16:42:51
User entered '2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 1992'	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '1992'	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\23.0.	Coder Import (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)	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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Nov 2019'	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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)	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)	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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Nov 2019'	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - 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 'insomnia'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2010'	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2010'	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2015'	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2015'	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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)	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)	29 Aug 2020 20:46:08
User entered 'DIABETIC RETINOPATHY LEFT EYE' reason for change: Data Entry Error	(b) (4) Heather Douds (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)	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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2019'	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2019'	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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 18:54:48
User entered 'low back pain'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2015'	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2015'	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2020'	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2020'	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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 'right shoulder dislocation'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	29 Aug 2020 18:56:22
User entered 'UN UNK 1951' reason for change:	Mikayla Frye (b) (4)	29 Aug 2020 18:56:22
Data Entry Error	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	29 Aug 2020 18:55:26
User entered 'un UNK 1950'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
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: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '24 Jan 2012'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2012'	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2012'	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2008'	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2008'	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:55
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) (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) (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) (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) (b) (4)	28 Oct 2020 19:06:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 19:06:12
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 19:06:12
User entered 'sensory DIABETIC NEUROPATHY' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
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
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

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jul 2014'	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '30 Jun 2019'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '10 Oct 2011'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '31 Oct 2011'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:21
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Oct 2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Oct 2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '12 Oct 2011'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '31 Oct 2011'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:46
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Oct 2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Oct 2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '13 Jan 2014'	Cassandra Zehenny (b) (4)	(b) (4)

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Apr 2016'	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2016'	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:14
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Nov 2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Nov 2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Investigations, HLGT: 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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jun 2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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)	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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '08 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:04
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:04
	(b) (4)	

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Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:55
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) (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) (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) (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Jan 2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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)	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)	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)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '20 Apr 2018'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Apr 2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'Apr 2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
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) (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) (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) (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 21:15:58
User entered 'recurrent urinary tract infections'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:40
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '08:10'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '29 Aug 2020 08:10'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '68.5' in	(b) (4) 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: 10 Jun 2021 08:15:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '181' lb	(b) (4) 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: 10 Jun 2021 08:15:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
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: 10 Jun 2021 08:15:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
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: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'bpm'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'breaths/min'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20

US3552232

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:01

US3552232

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:01

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'VISIT1'	System	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:15:41

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '188834'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 15:15:41

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:38:52
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	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: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) 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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'bpm'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'breaths/min'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (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) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) 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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'bpm'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'breaths/min'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '10:40'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered '29 Aug 2020 10:40'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'ONCE'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '29 Aug 2020'	(b) (4) 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: 10 Jun 2021 08:15:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) 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: 10 Jun 2021 08:15:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '10:05'	(b) (4) 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: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
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: 10 Jun 2021 08:15:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
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: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered empty.	(b) (4) 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: 10 Jun 2021 08:15:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered empty.	System	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	05 Sep 2020 16:48:12

US3552232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'I'	System	05 Sep 2020 16:48:12

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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' User entered '97.8'	System	04 Sep 2020 17:20:07
	System	04 Sep 2020 17:20:07

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 15:35:29
User entered '5 Sep 2020'	Joan Siegner (b) (4) (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'l'	System	12 Sep 2020 18:55:40

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered '12 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:30

US3552232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'I'	System	19 Sep 2020 17:18:30

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered '19 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'I'	System	13 Oct 2020 20:02:36

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'VISIT2'	System	13 Oct 2020 20:02:51

US3552232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'I'	System	13 Oct 2020 20:02:58

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered 'Subject was hospitalized and was unable to be reached by phone' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Jan 2021 17:53:49
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: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'l'	System	13 Oct 2020 20:03:39

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'l'	System	19 Oct 2020 14:35:26

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '19 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'l'	System	30 Oct 2020 18:20:18

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '30 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'VISIT3'	System	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	30 Oct 2020 18:48:48
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '30 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	30 Oct 2020 18:48:48
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '98.0' F reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	30 Oct 2020 18:48:48
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: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	30 Oct 2020 18:23:05
	(b) (4)	
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Oct 2020 18:21:41
	(b) (4)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered '30 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:23:05
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:41

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:55
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) (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) (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) (b) (4)	30 Oct 2020 18:21:57

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
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: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:50

US3552232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:17:01
User entered 'I'	System	18 Nov 2020 15:53:50

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:10:07
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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2020-11-30T07:15:31', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5815711d-d412-42ad-9227-2f10cb92f340'	System	30 Nov 2020 13:16:07
User entered 'No (N)'	System	30 Nov 2020 13:16:07

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2020-11-30T07:15:37', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5815711d-d412-42ad-9227-2f10cb92f340'	System	30 Nov 2020 13:16:07
User entered 'No (N)'	System	30 Nov 2020 13:16:07

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-11-30T07:16:01', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5815711d-d412-42ad-9227-2f10cb92f340'	System	30 Nov 2020 13:16:07
User entered '30 Nov 2020 07:16:01'	System	30 Nov 2020 13:16:07

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2020-12-07T11:02:09', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70ffa689-c824-48d2-ae15-90f01dd0632f'	System	07 Dec 2020 17:02:22
User entered 'No (N)'	System	07 Dec 2020 17:02:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2020-12-07T11:02:14', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70ffa689-c824-48d2-ae15-90f01dd0632f'	System	07 Dec 2020 17:02:22
User entered 'No (N)'	System	07 Dec 2020 17:02:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-12-07T11:02:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70ffa689-c824-48d2-ae15-90f01dd0632f' User entered '07 Dec 2020 11:02:20'	System	07 Dec 2020 17:02:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2020-12-17T14:00:30', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f4e35765-4fb4-496d-b136-5e757dd90ca1'	System	17 Dec 2020 20:01:04
User entered 'No (N)'	System	17 Dec 2020 20:01:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2020-12-17T14:00:51', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f4e35765-4fb4-496d-b136-5e757dd90ca1'	System	17 Dec 2020 20:01:04
User entered 'No (N)'	System	17 Dec 2020 20:01:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-12-17T14:01:01', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f4e35765-4fb4-496d-b136-5e757dd90ca1'	System	17 Dec 2020 20:01:04
User entered '17 Dec 2020 14:01:01'	System	17 Dec 2020 20:01:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2020-12-22T11:52:17', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1435379d-9867-4303-b348-799eb16ef650'	System	22 Dec 2020 17:52:35
User entered 'No (N)'	System	22 Dec 2020 17:52:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2020-12-22T11:52:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1435379d-9867-4303-b348-799eb16ef650'	System	22 Dec 2020 17:52:35
User entered 'No (N)'	System	22 Dec 2020 17:52:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-12-22T11:52:30', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1435379d-9867-4303-b348-799eb16ef650'	System	22 Dec 2020 17:52:35
User entered '22 Dec 2020 11:52:30'	System	22 Dec 2020 17:52:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2020-12-28T12:34:18', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cfb10c12-ad9d-431b-b502-fd3c35517f8a'	System	28 Dec 2020 18:34:36
User entered 'No (N)'	System	28 Dec 2020 18:34:36

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2020-12-28T12:34:23', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cfb10c12-ad9d-431b-b502-fd3c35517f8a'	System	28 Dec 2020 18:34:36
User entered 'No (N)'	System	28 Dec 2020 18:34:36

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-12-28T12:34:29', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cfb10c12-ad9d-431b-b502-fd3c35517f8a' User entered '28 Dec 2020 12:34:29'	System	28 Dec 2020 18:34:36

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-01-04T17:02:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e53315ce-4783-4186-9dfa-3a14e9dc7dc7'	System	04 Jan 2021 23:03:00
User entered 'No (N)'	System	04 Jan 2021 23:03:00

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-01-04T17:02:25', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e53315ce-4783-4186-9dfa-3a14e9dc7dc7'	System	04 Jan 2021 23:03:00
User entered 'No (N)'	System	04 Jan 2021 23:03:00

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-01-04T17:02:30', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e53315ce-4783-4186-9dfa-3a14e9dc7dc7'	System	04 Jan 2021 23:03:00
User entered '04 Jan 2021 17:02:30'	System	04 Jan 2021 23:03:00

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-01-11T13:19:31', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3af3ba59-291e-4109-bb16-0980cde879dd'	System	11 Jan 2021 19:19:51
User entered 'No (N)'	System	11 Jan 2021 19:19:51

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-01-11T13:19:35', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3af3ba59-291e-4109-bb16-0980cde879dd'	System	11 Jan 2021 19:19:51
User entered 'No (N)'	System	11 Jan 2021 19:19:51

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-01-11T13:19:45', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3af3ba59-291e-4109-bb16-0980cde879dd' User entered '11 Jan 2021 13:19:45'	System	11 Jan 2021 19:19:51
	System	11 Jan 2021 19:19:51

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-01-22T09:00:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '84c4da65-f142-4c9a-ace1-c2b83352b0d4'	System	22 Jan 2021 15:00:22
User entered 'No (N)'	System	22 Jan 2021 15:00:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-01-22T09:00:11', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '84c4da65-f142-4c9a-ace1-c2b83352b0d4'	System	22 Jan 2021 15:00:22
User entered 'No (N)'	System	22 Jan 2021 15:00:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-01-22T09:00:19', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '84c4da65-f142-4c9a-ace1-c2b83352b0d4'	System	22 Jan 2021 15:00:22
User entered '22 Jan 2021 09:00:19'	System	22 Jan 2021 15:00:22

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-01-26T11:42:39', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6cf3a3c0-8f66-4c3b-bc17-c44be517fd72'	System	26 Jan 2021 18:40:04
User entered 'No (N)'	System	26 Jan 2021 18:40:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-01-26T11:42:44', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6cf3a3c0-8f66-4c3b-bc17-c44be517fd72'	System	26 Jan 2021 18:40:04
User entered 'No (N)'	System	26 Jan 2021 18:40:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-01-26T11:42:49', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6cf3a3c0-8f66-4c3b-bc17-c44be517fd72'	System	26 Jan 2021 18:40:04
User entered '26 Jan 2021 11:42:49'	System	26 Jan 2021 18:40:04

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-02-01T08:12:47', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7890c71b-fb9a-42fe-b9c3-ffd2a94f6939'	System	02 Feb 2021 21:23:16
User entered 'No (N)'	System	02 Feb 2021 21:23:16

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-02-02T15:23:03', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7890c71b-fb9a-42fe-b9c3-ffd2a94f6939'	System	02 Feb 2021 21:23:16
User entered 'No (N)'	System	02 Feb 2021 21:23:16

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-02-02T15:23:14', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7890c71b-fb9a-42fe-b9c3-ffd2a94f6939'	System	02 Feb 2021 21:23:16
User entered '02 Feb 2021 15:23:14'	System	02 Feb 2021 21:23:16

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-02-08T03:02:23', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'beb5bd42-d3e1-40c0-82eb-96eed6c927d0'	System	08 Feb 2021 09:02:42
User entered 'No (N)'	System	08 Feb 2021 09:02:42

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-02-08T03:02:29', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'beb5bd42-d3e1-40c0-82eb-96eed6c927d0'	System	08 Feb 2021 09:02:42
User entered 'No (N)'	System	08 Feb 2021 09:02:42

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-02-08T03:02:38', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'beb5bd42-d3e1-40c0-82eb-96eed6c927d0'	System	08 Feb 2021 09:02:42
User entered '08 Feb 2021 03:02:38'	System	08 Feb 2021 09:02:42

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-02-18T17:17:49', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f756f0af-5ad1-4a38-9e1f-cb05460a977e'	System	18 Feb 2021 23:21:35
User entered 'No (N)'	System	18 Feb 2021 23:21:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Have you been exposed to someone with 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: '2021-02-18T17:17:54', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f756f0af-5ad1-4a38-9e1f-cb05460a977e'	System	18 Feb 2021 23:21:35
User entered 'No (N)'	System	18 Feb 2021 23:21:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-02-18T17:18:03', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f756f0af-5ad1-4a38-9e1f-cb05460a977e'	System	18 Feb 2021 23:21:35
User entered '18 Feb 2021 17:18:03'	System	18 Feb 2021 23:21:35

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-02-23T09:17:24-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '306682f2-17ed-4b04-908d-d0223db294b1' User entered 'No (N)'	System	23 Feb 2021 15:17:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-02-23T09:17:29-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '306682f2-17ed-4b04-908d-d0223db294b1'	System	23 Feb 2021 15:17:41
User entered 'No (N)'	System	23 Feb 2021 15:17:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-02-23T09:17:37-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '306682f2-17ed-4b04-908d-d0223db294b1'	System	23 Feb 2021 15:17:41
User entered '23 Feb 2021 09:17:37'	System	23 Feb 2021 15:17:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-03-02T11:08:11-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'a64f92c0-ace2-45c9-8522-13e489297924'	System	02 Mar 2021 17:15:57
User entered 'No (N)'	System	02 Mar 2021 17:15:57

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-03-02T11:08:20-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'a64f92c0-ace2-45c9-8522-13e489297924'	System	02 Mar 2021 17:15:57
User entered 'No (N)'	System	02 Mar 2021 17:15:57

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-02T11:08:24-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'a64f92c0-ace2-45c9-8522-13e489297924'	System	02 Mar 2021 17:15:57
User entered '02 Mar 2021 11:08:24'	System	02 Mar 2021 17:15:57

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-03-09T02:33:19-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '16fea949-bda7-4b6c-b296-142f7cf42756'	System	09 Mar 2021 08:33:44
User entered 'No (N)'	System	09 Mar 2021 08:33:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-03-09T02:33:31-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '16fea949-bda7-4b6c-b296-142f7cf42756'	System	09 Mar 2021 08:33:44
User entered 'No (N)'	System	09 Mar 2021 08:33:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-09T02:33:41-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '16fea949-bda7-4b6c-b296-142f7cf42756' User entered '09 Mar 2021 02:33:41'	System	09 Mar 2021 08:33:44
	System	09 Mar 2021 08:33:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-03-15T10:32:23-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6888562c-39ed-49ac-ab5b-7d875afe7510'	System	15 Mar 2021 15:32:45
User entered 'No (N)'	System	15 Mar 2021 15:32:45

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Have you been exposed to someone with 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: '2021-03-15T10:32:29-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6888562c-39ed-49ac-ab5b-7d875afe7510'	System	15 Mar 2021 15:32:45
User entered 'No (N)'	System	15 Mar 2021 15:32:45

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-15T10:32:42-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6888562c-39ed-49ac-ab5b-7d875afe7510'	System	15 Mar 2021 15:32:45
User entered '15 Mar 2021 10:32:42'	System	15 Mar 2021 15:32:45

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-03-22T16:41:21-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cc5ba64d-d2a5-4f35-a1e3-4dac5d9dd8ee'	System	22 Mar 2021 21:41:38
User entered 'No (N)'	System	22 Mar 2021 21:41:38

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Have you been exposed to someone with 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: '2021-03-22T16:41:28-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cc5ba64d-d2a5-4f35-a1e3-4dac5d9dd8ee'	System	22 Mar 2021 21:41:38
User entered 'No (N)'	System	22 Mar 2021 21:41:38

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-22T16:41:33-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'cc5ba64d-d2a5-4f35-a1e3-4dac5d9dd8ee' User entered '22 Mar 2021 16:41:33'	System	22 Mar 2021 21:41:38
	System	22 Mar 2021 21:41:38

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-03-29T06:01:09-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498'	System	29 Mar 2021 11:02:26
User entered 'Yes (Y)'	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-03-29T06:01:18-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498'	System	29 Mar 2021 11:02:26
User entered 'No (N)'	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: '2021-03-29T06:01:32-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498'	System	29 Mar 2021 11:02:26
User entered 'No (N)'	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: '2021-03-29T06:01:40-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498'	System	29 Mar 2021 11:02:26
User entered 'Yes (Y)'	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Please 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: '2021-03-29T06:01:56-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498'	System	29 Mar 2021 11:02:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-29T06:02:14-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '6c1aced1-d8a1-47ba-8388-3dc7512cf498' User entered '29 Mar 2021 06:02:14'	System	29 Mar 2021 11:02:26
	System	29 Mar 2021 11:02:26

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-04-07T09:45:11-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a'	System	07 Apr 2021 14:46:06
User entered 'Yes (Y)'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-04-07T09:45:16-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a' User entered 'No (N)'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: '2021-04-07T09:45:21-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a'	System	07 Apr 2021 14:46:06
User entered 'No (N)'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: '2021-04-07T09:45:29-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a'	System	07 Apr 2021 14:46:06
User entered 'Yes (Y)'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Please 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: '2021-04-07T09:45:36-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a'	System	07 Apr 2021 14:46:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-04-07T09:45:44-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3434513b-0940-4003-a922-0e4b51cba39a'	System	07 Apr 2021 14:46:06
User entered '07 Apr 2021 09:45:44'	System	07 Apr 2021 14:46:06

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-04-16T12:26:16-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fc24215d-d3a5-4b79-91ec-a9dbf8daffc5'	System	16 Apr 2021 17:29:37
User entered 'No (N)'	System	16 Apr 2021 17:29:37

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

Have you been exposed to someone with 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: '2021-04-16T12:26:20-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fc24215d-d3a5-4b79-91ec-a9dbf8daffc5'	System	16 Apr 2021 17:29:37
User entered 'No (N)'	System	16 Apr 2021 17:29:37

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-04-16T12:26:25-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fc24215d-d3a5-4b79-91ec-a9dbf8daffc5'	System	16 Apr 2021 17:29:37
User entered '16 Apr 2021 12:26:25'	System	16 Apr 2021 17:29:37

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-04-23T10:16:08-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '73f3340f-ea1f-4ec9-a448-354c7687c2bf' User entered 'No (N)'	System	23 Apr 2021 15:16:23
	System	23 Apr 2021 15:16:23

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-04-23T10:16:13-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '73f3340f-ea1f-4ec9-a448-354c7687c2bf'	System	23 Apr 2021 15:16:23
User entered 'No (N)'	System	23 Apr 2021 15:16:23

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-04-23T10:16:19-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '73f3340f-ea1f-4ec9-a448-354c7687c2bf'	System	23 Apr 2021 15:16:23
User entered '23 Apr 2021 10:16:19'	System	23 Apr 2021 15:16:23

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: '2021-04-30T14:12:27-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd08be0cf-06ee-4e09-a04a-333cdd6fdab8'	System	30 Apr 2021 19:12:41
User entered 'No (N)'	System	30 Apr 2021 19:12:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Have you been exposed to someone with 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: '2021-04-30T14:12:31-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd08be0cf-06ee-4e09-a04a-333cdd6fdab8'	System	30 Apr 2021 19:12:41
User entered 'No (N)'	System	30 Apr 2021 19:12:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-04-30T14:12:35-05:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd08be0cf-06ee-4e09-a04a-333cdd6fdab8' User entered '30 Apr 2021 14:12:35'	System	30 Apr 2021 19:12:41
	System	30 Apr 2021 19:12:41

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:23:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-02T11:07:52-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '55e5b473-f46c-4c0f-bcb9-5aa150650cdb'	System	02 Mar 2021 17:15:43
User entered 'No (N)'	System	02 Mar 2021 17:15:43

US3552232

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:23:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2021-03-02T11:07:58-06:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '55e5b473-f46c-4c0f-bcb9-5aa150650cdb' User entered '02 Mar 2021 11:07:58'	System	02 Mar 2021 17:15:43
	System	02 Mar 2021 17:15:43

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered '18 Nov 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
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: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:55
User entered empty.	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:00:37

US3552232

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:16:55
User entered 'l'	System	22 Dec 2020 18:00:37

US3552232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:00:51

US3552232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered '22 Dec 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:00:51

US3552232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:00:51

US3552232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:00:51

US3552232

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:41:26

US3552232

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'l'	System	22 Jan 2021 15:41:26

US3552232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:41:36

US3552232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered '22 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:41:36

US3552232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:41:36

US3552232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:41:36

US3552232

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Feb 2021 17:23:25

US3552232

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'l'	System	18 Feb 2021 17:23:25

US3552232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:26
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Feb 2021 16:23:55

US3552232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:26
User entered '23 Feb 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Feb 2021 16:23:55

US3552232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Feb 2021 16:23:55

US3552232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:26:26
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Feb 2021 16:23:55

US3552232

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Feb 2021 16:23:59

US3552232

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'l'	System	23 Feb 2021 16:23:59

US3552232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:32:52

US3552232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:32:52

US3552232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Clinic (Clinic)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:32:52

US3552232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'VISIT4'	System	25 Mar 2021 20:32:52

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered 'No (N)'	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
	(b) (4)	
User entered '25 Mar 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered '11:00' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered '25 Mar 2021 11:00'	System	30 Mar 2021 19:33:20
User entered empty.	System	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered '98' F reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered 'Oral (Oral)' reason for change: Per	(b) (4)	
Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered '53' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'bpm'	System	30 Mar 2021 19:33:20
User entered empty.	System	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User entered '18' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'breaths/min'	System	30 Mar 2021 19:33:20
User entered empty.	System	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 06:18:15
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:55:30
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:12:03
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:33:20
User entered '180' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 19:33:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:26:35
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'mmHg'	System	30 Mar 2021 19:33:20
User entered empty.	System	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
	(b) (4)	
User entered '80' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:20
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	29 Mar 2021 21:01:09
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'mmHg'	System	30 Mar 2021 19:33:20
User entered empty.	System	29 Mar 2021 21:01:09

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44

US3552232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44

US3552232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:49
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:49
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
	(b) (4)	
User entered 'No (N)'	Heather Douds (b) (4)	25 Mar 2021 20:33:02
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:49
	(b) (4)	
User entered '25 Mar 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Mar 2021 19:33:49
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
	(b) (4)	
User entered empty.	Heather Douds (b) (4)	25 Mar 2021 20:33:02
	(b) (4)	

US3552232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:33:15

US3552232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:15

US3552232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:57:14
User entered '11:42'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:15

US3552232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered '25 Mar 2021 11:42'	System	25 Mar 2021 20:33:15

US3552232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:19

US3552232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:27:44
User entered 'I'	System	25 Mar 2021 20:33:19

US3552232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 15:35:30

US3552232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered '21 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 15:35:30

US3552232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 15:35:30

US3552232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Apr 2021 15:35:30

US3552232

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Apr 2021 15:36:26

US3552232

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Apr 2021 15:36:26

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:12

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:17
User entered '22 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:24

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:12

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:17
User entered '09:07'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:24

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:31
User entered '22 Jan 2021 09:07'	System	26 Jan 2021 19:28:24

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:12

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:17
User entered 'Safety Call (Safety Call)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:24

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:17
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:24

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 1 (Day 1)'	(b) (4) Heather Douds (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '18 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:29:17

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 2 (Day 2)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '19 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:40:52

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 3 (Day 3)'	(b) (4) Heather Douds (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '20 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:41:40

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 4 (Day 4)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '21 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 5 (Day 5)'	(b) (4) Heather Douds (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '22 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:42:56

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 6 (Day 6)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '23 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:43:32

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 7 (Day 7)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '24 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:12

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 8 (Day 8)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '25 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:44:53

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 9 (Day 9)'	(b) (4) Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '26 Jan 2021'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 19:20:28
User closed query 'Per source, T 97.7, and O2 - 99%. Please update entries. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:20:25
Query 'Per source, T 97.7, and O2 - 99%. Please update entries. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	02 Feb 2021 21:24:34
	(b) (4)	
DataPoint Un-verified.	Heather Douds (b) (4)	02 Feb 2021 21:24:22
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Feb 2021 21:24:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:43:53
	(b) (4), (b) (6)	
User opened query 'Per source, T 97.7, and O2 - 99%. Please update entries. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:42:32
User entered missing code ND - Not Done.	Heather Douds (b) (4)	26 Jan 2021 19:46:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 19:20:30
DataPoint Un-verified.	Heather Douds (b) (4)	02 Feb 2021 21:24:22
	(b) (4)	
User entered '97.7' F reason for change: Data Entry Error	Heather Douds (b) (4)	02 Feb 2021 21:24:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered missing code ND - Not Done.	Heather Douds (b) (4)	26 Jan 2021 19:46:31
	(b) (4)	

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Moderate (Moderate)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Moderate (Moderate)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Severe (Severe)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:46:31

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 10 (Day 10)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '27 Jan 2021'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '99'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97.6' F	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	27 Jan 2021 19:13:22

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 11 (Day 11)'	(b) (4) Heather Douds (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '28 Jan 2021'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '98'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97.7' F	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 12 (Day 12)' reason for change: New Information	(b) (4) Heather Douds (b) (4)	29 Jan 2021 16:12:02
User entered 'Day 11 (Day 11)' reason for change: New Information	(b) (4) Heather Douds (b) (4)	29 Jan 2021 16:11:44
User entered empty.	(b) (4) Heather Douds (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 03:29:46
User entered '29 Jan 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
Query 'Data is required. Please complete.' answered with 'date has not yet occurred' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:02:16
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 15:44:15
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Heather Doubs (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '99' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	29 Jan 2021 16:11:44
User entered empty.	System	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97.6' F reason for change: New Information	Heather Douds (b) (4)	29 Jan 2021 16:11:44
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Jan 2021 15:44:15
	(b) (4)	

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:11:44
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Jan 2021 15:44:15

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 13 (Day 13)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '30 Jan 2021'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '98' F	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'Mild (Mild)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:26:55

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 14 (Day 14)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '31 Jan 2021'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97.8' F	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:27:44

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 15 (Day 15)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '01 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '98'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '98.0' F	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:29:34

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Stanley Dublin (b) (4)	05 Feb 2021 16:00:49
User entered 'Day 15 (Day 15)'	(b) (4)	
	Mikayla Frye (b) (4)	02 Feb 2021 15:14:57
	(b) (4)	

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '02 Feb 2021'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '0'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '98'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered '97.6' F	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:53
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	02 Feb 2021 15:14:57

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	05 Feb 2021 16:00:49
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Feb 2021 20:06:31
User entered 'Day 9 (Day 9)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered '03 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered '0'	Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered '97'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered '97.8' F	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Feb 2021 16:20:05

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 18 (Day 18)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered '04 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered '0'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered '98'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered '97.8' F	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:56
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 15:24:01

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 19 (Day 19)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered '05 Feb 2021'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered '0'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered '97'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:59
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	05 Feb 2021 16:00:33

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 20 (Day 20)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered '06 Feb 2021'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered '97'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (20)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:39:36

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 21 (Day 21)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered '07 Feb 2021'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered '97'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (21)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:43:18

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'Day 22 (Day 22)'	(b) (4)	
	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4)	
	Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4)	08 Feb 2021 15:44:09
	(b) (4)	

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered '08 Feb 2021'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered '0'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered '99'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User entered '%'	System	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Stanley Doublin (b) (4)	08 Feb 2021 15:44:09
	(b) (4)	

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered '97.8' F	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Symptom Log (22)

Generated On: 10 Jun 2021 08:15:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:31:11
User entered 'None (None)'	Cassandra Zehenny (b) (4)	08 Feb 2021 16:14:18
DataPoint activated with code reason code Data required.	(b) (4) Cassandra Zehenny (b) (4)	08 Feb 2021 16:13:29
DataPoint inactivated with code reason code Data not required.	Stanley Doublin (b) (4) (b) (4)	08 Feb 2021 15:44:09

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:02
User entered '26 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:05
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:07
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 07:04:24
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	27 Jan 2021 15:28:45
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:08
User entered '26 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:11
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:12

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:37
User closed query 'Please remove local lab entries as central lab sample resulted pos ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:17:33
Query 'Please remove local lab entries as central lab sample resulted pos ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	02 Feb 2021 21:29:18
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Feb 2021 21:29:14
User opened query 'Please remove local lab entries as central lab sample resulted pos ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:29:12
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	01 Feb 2021 15:32:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 15:32:47
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	01 Feb 2021 15:32:36
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:09:57
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:39
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Feb 2021 21:29:14
User entered 'SAINT LOUIS UNIVERSITY CENTER FOR VACCINE DEVELOPMENT' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 15:32:36
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Jan 2021 16:09:57
User entered 'Saint Louis University Vaccine Development Center'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 19:17:42
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	02 Feb 2021 21:29:14
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	01 Feb 2021 15:32:36
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	29 Jan 2021 16:09:57
	(b) (4)	
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	27 Jan 2021 15:28:45
	(b) (4)	

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:03:54
User entered 'I'	System	27 Jan 2021 15:28:45

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

US3552232

Folder: Covid-19 Assessment 22 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:15:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:29:30

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Folder: Covid-19 Assessment 22 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:15:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:04:21
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:40:14
User closed query 'Next assessment not generated. please consider updating to No. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:39:59
Query 'Next assessment not generated. please consider updating to No. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	13 Apr 2021 14:22:06
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	13 Apr 2021 14:22:02
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Apr 2021 14:22:02
User opened query 'Next assessment not generated. please consider updating to No. ' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:40
	(b) (4), (b) (6)	12 Apr 2021 19:57:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:31:34
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	27 Jan 2021 15:29:38
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:35
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:35
User entered '28 Jan 2021'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Feb 2021 18:46:38
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:30:43
Query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks' answered with 'As previously stated, this is something that should be acquired from the lab per Site Remote Monitor. This has been resulted from some time.' (Site from DM).	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:35:01
User opened query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:11:53
User closed query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:11:53
Query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample has been shipped; please review with lab for accession number' (Site from DM).	Heather Douds (b) (4) (b) (4)	01 Mar 2021 17:17:00
User opened query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:25:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:24:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'results already received. please check again' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 09 Feb 2021 22:15:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 06:48:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:38
User entered '29 Jan 2021'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Feb 2021 18:46:42
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 07:36:06
Query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks ? ' answered with 'As previously stated, this is something that should be acquired from the lab per Site Remote Monitor. This has been resulted from some time. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	02 Mar 2021 16:35:08
User opened query 'Per GCL Lab recon: Saliva: Requery1: Please provide Accession number for reference so that confirmation can be done with PPD central lab.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:14:17
User closed query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:14:17
Query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample has been shipped and has already resulted; please review with lab for accession number' (Site from DM).	Heather Douds (b) (4) (b) (4)	01 Mar 2021 17:17:16
User opened query 'Per GCL Lab recon: Saliva: Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:25:41
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:25:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'results already received. please check again' (Site from DM).	Cassandra Zehenny (b) (4)	09 Feb 2021 22:15:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 06:49:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:42
User entered '01 Feb 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Feb 2021 16:51:01
User entered '1 Feb 2021'	Heather Douds (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 22:12:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 22:12:28
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	04 Feb 2021 22:12:28
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:42
User entered empty.	Heather Douds (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:32
User entered '03 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 22:12:28
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:12

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 21:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:58:53
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	08 Feb 2021 21:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:42
User entered empty.	Heather Douds (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:32
User entered '08 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	08 Feb 2021 21:58:53
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Data of saliva collection day 21 was provided, please update accordingly. thanks' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:30:47
User signature succeeded.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
Query 'Per ETRTR: Data of saliva collection day 21 was provided, please update accordingly. thanks' answered with 'updated thank you' (Site from CRA). User entered 'Yes (Y)' reason for change: New Information	sharon frey (b) (4) (b) (4) Cassandra Zehenny (b) (4) (b) (4)	27 Feb 2021 17:54:32 22 Feb 2021 19:55:01 22 Feb 2021 19:54:46
User opened query 'Per ETRTR: Data of saliva collection day 21 was provided, please update accordingly. thanks' (Site from CRA). User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 19:29:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 16:41:01
User entered 'No (N)' reason for change: New Information	System	16 Feb 2021 16:41:01
User opened query 'Data is required. Please complete.' (Site from System). User entered empty.	Cassandra Zehenny (b) (4) (b) (4) System Heather Douds (b) (4) (b) (4)	16 Feb 2021 16:41:01 01 Feb 2021 17:45:42 01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	27 Feb 2021 17:54:32
User entered '15 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	22 Feb 2021 19:54:46
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Feb 2021 19:54:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 19:54:46
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	22 Feb 2021 19:54:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:42
User entered empty.	Heather Douds (b) (4)	01 Feb 2021 17:45:42

US3552232

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:48
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:14:32
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'accession # 1F60DN4' (Site from DM).	(b) (4)	
	Cassandra Zehenny (b) (4)	26 Feb 2021 22:49:56
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 10:06:52
User entered '22 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	22 Feb 2021 19:54:46
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	01 Feb 2021 17:45:42
	(b) (4)	

US3552232

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:38
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:38
User entered '26 Jan 2021'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:38
User entered 'Home (Home)'	Stanley Doublin (b) (4) (b) (4)	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered 'SICKD1'	System	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '26 Jan 2021'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '11:00'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered '26 Jan 2021 11:00'	System	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered missing code ND - Not Done.	Stanley Doublin (b) (4)	26 Jan 2021 19:03:38
DataPoint set to visible.	(b) (4) System	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered missing code ND - Not Done.	Stanley Doublin (b) (4)	26 Jan 2021 19:03:38
DataPoint set to visible.	(b) (4) System	26 Jan 2021 19:02:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '97.7' F	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered empty.	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '54'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered 'bpm'	System	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '18'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered 'breaths/min'	System	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 10:29:54
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'NCS' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Feb 2021 17:25:51
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:17:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '160'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered 'mmHg'	System	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:54
User entered '80'	Stanley Doublin (b) (4) (b) (4)	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User entered 'mmHg'	System	26 Jan 2021 19:03:38

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44

US3552232

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44

US3552232

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:45:03
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:46

US3552232

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:45:03
User entered empty.	Stanley Dublin (b) (4) (b) (4)	26 Jan 2021 19:03:46

US3552232

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:15:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:45:16
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:00

US3552232

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:45:16
User entered '26 Jan 2021'	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:28:00

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:07
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered 'SICKD28'	System	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '11:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered '22 Feb 2021 11:45'	System	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '68.5' in	(b) (4) Stanley Dublin (b) (4)	22 Feb 2021 19:37:07
DataPoint set to visible.	(b) (4) System	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '171' lb	(b) (4) Stanley Dublin (b) (4)	22 Feb 2021 19:37:07
DataPoint set to visible.	(b) (4) System	22 Feb 2021 19:35:52

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '98.1' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered 'bpm'	System	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered 'breaths/min'	System	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:39:37
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'NCS' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	26 Feb 2021 22:50:14
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:36:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:22:31
User entered '168' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:37:26
User entered '187'	Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered 'mmHg'	System	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:35
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '76' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	22 Feb 2021 19:37:26
User entered '80'	(b) (4)	
	Stanley Doublin (b) (4)	22 Feb 2021 19:37:07
	(b) (4)	

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
User entered 'mmHg'	System	22 Feb 2021 19:37:07

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:40
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:32

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:40
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:32

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:15:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:48

US3552232

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:15:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 20:01:44
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:37:48

US3552232

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:03

US3552232

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:03

US3552232

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:03

US3552232

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 13:09:03

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:21
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	18 Mar 2021 18:44:00
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:57:42

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:31:21
User entered 'Amendment 6 or later (Amendment 6 or later)'	Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 18:44:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:57:42

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Not Administered (NA)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'I'	System	01 Mar 2021 13:09:58

US3552232

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'I'	System	01 Mar 2021 13:09:58

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	01 Mar 2021 13:10:49
DataPoint set to visible.	System	01 Mar 2021 13:09:58

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	01 Mar 2021 13:10:49
DataPoint set to visible.	System	01 Mar 2021 13:09:58

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '14:39'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '26 Feb 2021 14:39'	System	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '97.2' F	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'bpm'	System	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '18'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'breaths/min'	System	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '157'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '67'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:10:49

US3552232

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered empty.	System	01 Mar 2021 13:10:49
DataPoint set to visible.	System	01 Mar 2021 13:09:58

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '15:57'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '26 Feb 2021 15:57'	System	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '55'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'bpm'	System	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '18'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'breaths/min'	System	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '150'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:57:26
User entered '68'	Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:12

US3552232

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mmHg'	System	01 Mar 2021 13:18:12

US3552232

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:26

US3552232

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:26

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'mRNA-1273'	System	01 Mar 2021 13:18:42
DataPoint set to visible.	System	01 Mar 2021 13:09:58

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '15:27'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '26 Feb 2021 15:27'	System	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'ONCE'	System	01 Mar 2021 13:18:42

US3552232

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

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 13:18:42

US3552232

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:59

US3552232

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:59

US3552232

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '14:25'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:18:59

US3552232

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '26 Feb 2021 14:25'	System	01 Mar 2021 13:18:59

US3552232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:20:34

US3552232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:20:34

US3552232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '14:30'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:20:34

US3552232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered '26 Feb 2021 14:30'	System	01 Mar 2021 13:20:34

US3552232

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

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 13:20:39

US3552232

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

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:20
User entered 'I'	System	01 Mar 2021 13:20:39

US3552232

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Mar 2021 16:11:51

US3552232

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered '5 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Mar 2021 16:11:51

US3552232

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Heather Douds (b) (4)	05 Mar 2021 16:11:51

US3552232

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Mar 2021 16:11:51

US3552232

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:57:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Mar 2021 16:11:55

US3552232

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User entered 'l'	System	05 Mar 2021 16:11:55

US3552232

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:13
User entered 'I'	System	05 Mar 2021 16:11:55
DataPoint set to visible.	System	05 Mar 2021 16:11:55

US3552232

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:27

US3552232

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:27

US3552232

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Clinic (Clinic)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:33:27

US3552232

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'OLD29'	System	25 Mar 2021 20:33:27

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '11:00'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered '25 Mar 2021 11:00'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '98' F	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Oral (Oral)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '53'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'bpm'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '18'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'breaths/min'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '180'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'mmHg'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '80'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'mmHg'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '12:43'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered '25 Mar 2021 12:43'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '98.1' F	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Oral (Oral)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '52'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'bpm'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '18'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'breaths/min'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '184'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'mmHg'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '80'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'mmHg'	System	25 Mar 2021 20:34:55

US3552232

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:03

US3552232

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:03

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered empty.	(b) (4) Heather Douds (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'mRNA-1273'	System	25 Mar 2021 20:35:23
DataPoint set to visible.	System	05 Mar 2021 16:11:55

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered '12:13'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered '25 Mar 2021 12:13'	System	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'ONCE'	System	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'INTRAMUSCULAR'	System	25 Mar 2021 20:35:23

US3552232

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:57:14
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Mar 2021 20:35:28

US3552232

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:33:50
User entered 'l'	System	25 Mar 2021 20:35:28

US3552232

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Apr 2021 17:02:01

US3552232

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	01 Apr 2021 19:34:08
User entered '1 Apr 2021'	(b) (4)	
	Stanley Doublin (b) (4)	01 Apr 2021 17:02:01
	(b) (4)	

US3552232

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Apr 2021 17:02:01

US3552232

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Apr 2021 17:02:01

US3552232

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Apr 2021 17:02:05

US3552232

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Apr 2021 17:02:05

US3552232

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:17

US3552232

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered '22 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:17

US3552232

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:17

US3552232

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	22 Apr 2021 18:35:17

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:35:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:35:21

US3552232

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:25

US3552232

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:25

US3552232

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:35

US3552232

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered '22 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:35

US3552232

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:05
User entered '12:56'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Apr 2021 18:35:35

US3552232

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 12:56'	System	22 Apr 2021 18:35:35

US3552232

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:15:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:33:05
Query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'No AE necessary' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Apr 2021 16:18:24
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:10:03
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	29 Sep 2020 13:21:58

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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.	Coder Import (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 07:48:15
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.	(b) (4), (b) (6)	14 Oct 2020 15:30:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 16:55:37
Data point term sent to Coder	(b) (4)	
User entered 'Pneumonia'	System	28 Sep 2020 16:55:04
	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	15 Oct 2020 14:21:37
User entered '26 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (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) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:46:29
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:24:27
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4) (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) (b) (4)	03 Nov 2020 16:48:59
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:48:35
User entered '08 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4) (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) (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

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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).		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) (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).	System	28 Sep 2020 16:54:27
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: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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.	Heather Douds (b) (4)	20 Nov 2020 19:23:16
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 19:23:16
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
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
User entered '8 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	12 Oct 2020 20:26:12
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
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
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
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
User entered empty.	Heather Douds (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:43:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	08 Oct 2020 18:59:48
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
Signature has been broken.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 17:17:32
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:43:11
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:43:12
User entered 'l'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:46:48
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:23:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (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) (b) (4)	03 Nov 2020 16:49:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (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) (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) (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) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:46:49
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:23:16
User entered empty; reason for change New Information	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:23:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:36
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:48:35
User entered 'Subject has completed his antibiotic trials, but remains on home oxygen that is being weaned. Currently on IL NC.' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:48:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:18
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review narrative = Chest Xray as this Diagnostic Procedure is not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:58:08
Query 'Per DM CLR: Please review narrative = Chest Xray as this Diagnostic Procedure is not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify. ' answered with 'Not considered a procedure per PI, non invasive' (Site from DM).	Heather Douds (b) (4)	25 Jan 2021 18:54:02
User opened query 'Per DM CLR: Please review narrative = Chest Xray as this Diagnostic Procedure is not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	24 Jan 2021 14:48:47
User closed query 'Per DM CLR: SAE Narrative = X RAY ON 10/15. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. '(Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:28:14
Query 'Per DM CLR: SAE Narrative = X RAY ON 10/15. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:15:43
User opened query 'Per DM CLR: SAE Narrative = X RAY ON 10/15. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. '(Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:53:52
User closed query 'Per DM CLR: Narrative indicates that the subject had X-Ray, Cultures, CT, & Holter. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:07:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had X-Ray, Cultures, CT, & Holter. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify. ' answered with 'Everything listed is a type of non-invasive diagnostic imaging, not procedures' (Site from DM). User opened query 'Per DM CLR: Narrative indicates that the subject had X-Ray, Cultures, CT, & Holter. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify. (Site from DM). DataPoint Verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 19:31:57
DataPoint Un-verified.	(b) (4), (b) (6)	28 Nov 2020 05:17:36
	(b) (4), (b) (6)	23 Nov 2020 15:46:51
	Heather Douds (b) (4)	20 Nov 2020 19:23:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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)	20 Nov 2020 19:23:16

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[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) (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) (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
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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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)	21 Oct 2020 14:49:18

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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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: 10 Jun 2021 08:15:12

[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)	15 Oct 2020 14:35:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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)	14 Oct 2020 15:30:16

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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)	12 Oct 2020 20:26:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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)	06 Oct 2020 17:12:29
reason for change: Data Entry Error		

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	29 Sep 2020 13:22:22

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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, HLG: 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: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:24
DataPoint Un-verified.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:30:09
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (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) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:47:04
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:24:05
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4) (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 Doublin (b) (4) (b) (4)	30 Oct 2020 18:30:23
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 18:30:09
User entered '17 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (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) (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

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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 'I'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:44:53
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	08 Oct 2020 19:00:14
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4) (b) (4), (b) (6)	17 Dec 2020 08:52:14 15 Dec 2020 19:18:49 12 Dec 2020 06:54:06
User entered 'I'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:45:00 28 Sep 2020 16:58:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Dublin (b) (4) (b) (4)	30 Oct 2020 18:30:37
DataPoint Un-verified.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:30:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Dublin (b) (4) (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) (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) (b) (4)	28 Sep 2020 16:58:50

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Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: SAE Narrative = SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 10:58:00
User closed query 'Per DM CLR: SAE Narrative = X RAY ON 10/15 However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:50:44
Query 'Per DM CLR: SAE Narrative = X RAY ON 10/15 However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'X RAY is not a conprocedure' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:01:02
Query 'Per DM CLR: SAE Narrative = SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'already recorded as separate AE ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:00:54
User opened query 'Per DM CLR: SAE Narrative = X RAY ON 10/15 However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:04:42
User opened query 'Per DM CLR: SAE Narrative = SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:04:37

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[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 14:25:16
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. Please leave query open until information is available.' answered with 'These additional tests were not performed. Thank you.' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	04 Dec 2020 15:58:00
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:10:27
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)	01 Dec 2020 13:18:37
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 'All information is up to date as of now. Will update with any new information after patient's 3 month follow up' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:33:04
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)	25 Nov 2020 21:06:17

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Folder: Adverse Events

Form: Adverse Events (3)

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[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[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)	20 Nov 2020 19:24:05

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Folder: Adverse Events

Form: Adverse Events (3)

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[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)	28 Oct 2020 17:45:06

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Folder: Adverse Events

Form: Adverse Events (3)

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[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)	21 Oct 2020 14:49:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[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		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[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

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Folder: Adverse Events

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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		

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[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)	12 Oct 2020 20:27:29

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[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[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)	06 Oct 2020 17:12:46

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (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.	Coder Import (b) (4) (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) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:34
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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:56:28
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (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) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	(b) (4) 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) (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) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:38
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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:43
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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).	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 20:48:55
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	12 Oct 2020 20:47:19
User entered 'I'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:47
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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:51
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: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:52
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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:54
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:55
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:56
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:58
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:47:00
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:47:01
User entered 'None (NONE)' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:20:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:47:06
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:47:08
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:47:10
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	03 Nov 2020 16:58:19
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:55:46
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 16:55:46
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) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:05
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (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	Cassandra Zehenny (b) (4) (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) (b) (4)	12 Oct 2020 20:47:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Oct 2020 19:03:29
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 19:03:25

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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)	19 Oct 2020 16:14:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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)	15 Oct 2020 14:36:05

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:27
User coded data point as SOC: Cardiac disorders, HLT: 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: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:32
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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:36
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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:38
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	13 Oct 2020 13:49:44
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: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:41
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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:43
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:46
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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:49
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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:50
User entered 'I'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:53
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:35:55
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:01
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:03
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:04
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:21:24
DataPoint Verified.	(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

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:09
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:11
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:16
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= TROPONINS ELEVATED (Blood work up) if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:48:49
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CULTURES ARE STILL PENDING FROM BRONCH if this should be recorded. Else, re-clarify. (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:19:16
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST CT if this should be recorded. Else, re-clarify. (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:18:10
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= ECHO if this should be recorded. Else, re-clarify. (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:18:06
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= HOLTER MONITOR if this should be recorded. Else, re-clarify. (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:16:14

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST X RAYS (9/26 & 10/6 if this should be recorded. Else, re-clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:16:09
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative=CARDIOLOGY WORKUP if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:16:06
User closed query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= NEGATIVE RESPIRATORY PANEL if this should be recorded. Else, re-clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 02:56:26
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= NEGATIVE RESPIRATORY PANEL if this should be recorded. Else, re-clarify. ' answered with 'Panels are not procedures.' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 20:48:01
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST CT if this should be recorded. Else, re-clarify. ' answered with 'Please see previous responses; PI does not consider this to be a procedure as it is not invasive and will not list it as such. Captured in narrative. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 20:47:46

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Audit	User	Time (GMT)
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= TROPONINS ELEVATED (Blood work up) if this should be recorded. Else, re-clarify.' answered with 'Troponins are not a procedure' (Site from DM).	Heather Douds (b) (4)	22 Feb 2021 20:47:42
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= ECHO if this should be recorded. Else, re-clarify. ' answered with 'Please see previous responses; PI does not consider this to be a procedure as it is not invasive and will not list it as such. Captured in narrative. ' (Site from DM).	Heather Douds (b) (4)	22 Feb 2021 20:47:24
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= HOLTER MONITOR if this should be recorded. Else, re-clarify. ' answered with 'Please see previous responses; PI does not consider this to be a procedure as it is not invasive and will not list it as such. Captured in narrative. ' (Site from DM).	Heather Douds (b) (4)	22 Feb 2021 20:47:19
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CULTURES ARE STILL PENDING FROM BRONCH if this should be recorded. Else, re-clarify. ' answered with 'Please review; bronch is listed as a procedure. Cultures are not a procedure. ' (Site from DM).	Heather Douds (b) (4)	22 Feb 2021 20:47:13

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Audit	User	Time (GMT)
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST X RAYS (9/26 & 10/6 if this should be recorded. Else, re-clarify. ' answered with 'Please see previous responses; PI does not consider this to be a procedure as it is not invasive and will not list it as such. Captured in narrative. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 20:46:13
Query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative=CARDIOLOGY WORKUP if this should be recorded. Else, re-clarify.' answered with 'Please see previous responses; PI does not consider this to be a procedure as it is not invasive and will not list it as such. Captured in narrative. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 20:46:08
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= NEGATIVE RESPIRATORY PANEL if this should be recorded. Else, re-clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:34:34
User closed query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:34:34
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST CT if this should be recorded. Else, re-clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:34:09
User closed query 'Per DM CLR: SAE Narrative = CHEST CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:34:09

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EAB) (1725)

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= TROPONINS ELEVATED (Blood work up) if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:33:47
User closed query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:33:47
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= ECHO if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:33:09
User closed query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:33:09
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= HOLTER MONITOR if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:52
User closed query 'Per DM CLR: SAE Narrative = HOLTER MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:52
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CULTURES ARE STILL PENDING FROM BRONCH if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:24

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:24
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative= CHEST X RAYS (9/26 & 10/6 if this should be recorded. Else, re-clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:31:51
User closed query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:31:51
User opened query 'Per DM CLR: Response noted. However, please include DIAGNOSTIC Procedures in Con Procedure ecrf. Note, "diagnostic: is an available option in Con Proc ecrf. Review SAE Narrative=CARDIOLOGY WORKUP if this should be recorded. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:31:23
User closed query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:31:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 05:54:45
Query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:01:59

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Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = CHEST CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:56
Query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:54
Query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:51
Query 'Per DM CLR: SAE Narrative = HOLTER MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:49
Query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:46
Query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not medication' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:43
Query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:34
Query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Not procedure' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:01:31

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:07:02
User opened query 'Per DM CLR: SAE Narrative = CHEST CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:55
User opened query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:47
User opened query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:26
User opened query 'Per DM CLR: SAE Narrative = HOLTER MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:21
User opened query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:14
User opened query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:06:07
User opened query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 06:05:59

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 06:05:54
DataPoint Un-verified.	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:47:38 15 Oct 2020 14:36:25

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[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)	15 Oct 2020 14:36:25

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EAB) (1725)

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US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[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)	14 Oct 2020 15:36:17

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:37
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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:40
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:42
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:44
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: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	Cassandra Zehenny (b) (4)	09 Nov 2020 15:36:55
DataPoint Verified.	(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

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:47
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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:48
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:52
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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:55
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:57
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:36:58
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:00
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:06
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:08
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:22:04
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:14
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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)	15 Oct 2020 14:36:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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)	14 Oct 2020 15:37:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

2844 of 4452

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 08:23:03
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Data correct as entered, recorded from from hospital records' (Site from DM).	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:09:42
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:58:26
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:33
User coded data point as SOC: Renal and urinary disorders, HLGT: 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) (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.	Coder Import (b) (4) (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) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	Cassandra Zehenny (b) (4)	09 Nov 2020 15:37:23
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).	(b) (4), (b) (6)	04 Nov 2020 16:29:54
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).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:04:32
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)	28 Oct 2020 18:38:18
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:46
User entered '8 Oct 2020'	Heather Douds (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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)	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)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:38:55
User entered 'l'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:42:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 15:23:15
User entered 'None (NONE)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 15:23:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:11
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:33:56
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Per medical records, medications were adjusted to be less renal toxic, thereby treating with medication, though all medications were given for other indications. Data correct as entered.' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:15:33
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:58:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:14
User entered 'I'	Heather Douds (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:50:48
User closed query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:28:23
User closed query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:28:21
User closed query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:28:08
User closed query 'Per DM CLR: SAE Narrative = HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:28:05
User closed query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:28:03
User closed query 'Per DM CLR: SAE Narrative = CHEST CT . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:27:58
User closed query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:27:56

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:21:49
Query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:14:14
Query 'Per DM CLR: SAE Narrative = CHEST CT . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:14:07
Query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Troponins are a lab, not a procedure' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:12:20
Query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:11:58
Query 'Per DM CLR: SAE Narrative = HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:11:52

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Bronchoscopy is recorded appropriately' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:11:40
Query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Oxygen is not a medication' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:11:22
Query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non-invasive and not considered "procedure" per PI, data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:11:13
Query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Non invasive and therefore not considered a "procedure," data correct as entered' (Site from DM).	Heather Douds (b) (4)	15 Dec 2020 19:10:53
User opened query 'Per DM CLR: SAE Narrative = NEGATIVE RESPIRATORY PANEL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:59
User opened query 'Per DM CLR: SAE Narrative = CHEST CT . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:53
User opened query 'Per DM CLR: SAE Narrative = TROPONINS ELEVATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:47
User opened query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:41

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:33
User opened query 'Per DM CLR: SAE Narrative = CULTURES ARE STILL PENDING FROM BRONCH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:18
User opened query 'Per DM CLR: SAE Narrative = SUBJECT ON 8L/MIN O2. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:14
User opened query 'Per DM CLR: SAE Narrative = CHEST X RAYS (9/26 & 10/6). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:57:08
User opened query 'Per DM CLR: SAE Narrative = CARDIOLOGY WORKUP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:56:41
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

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Folder: Adverse Events

Form: Adverse Events (8)

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[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)	15 Oct 2020 14:40:10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:15
User coded data point as SOC: Gastrointestinal disorders, HLG: 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, HLG: 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 Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:08
User entered '27 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:06
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User entered empty.	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:03
User entered '27 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:59
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: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User entered empty.	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:56
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:53
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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:49
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: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:47
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: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

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Folder: Adverse Events

Form: Adverse Events (9)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:42
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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:41
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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:39
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: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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) Cassandra Zehenny (b) (4)	22 Nov 2020 16:13:57 19 Nov 2020 15:20:02
User entered 'None (NONE)' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 15:19:56
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.	Cassandra Zehenny (b) (4) (b) (4), (b) (6)	19 Nov 2020 15:19:56 19 Nov 2020 09:19:45
User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4), (b) (6) System	05 Nov 2020 21:43:33 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). User entered empty.	System Stanley Dublin (b) (4)	19 Oct 2020 14:44:27 19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:43:24
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: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User entered '0'	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54
User entered 'I'	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:22:54

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:14
User entered	System	02 Feb 2021 18:32:07
'USA-US089-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 18:32:07

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm if the subject received second dose of IP prior to the onset date of the AE. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:48:33
Query 'Per MM: Please confirm if the subject received second dose of IP prior to the onset date of the AE. ' answered with 'please reference EDC, as this information is present. Subject received dose #1 on 26 Feb, after COVID 19 diagnosis ' (Site from DM).	Cassandra Zehenny (b) (4)	18 Mar 2021 18:45:10
User opened query 'Per MM: Please confirm if the subject received second dose of IP prior to the onset date of the AE. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 16:32:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User closed query 'Please update term to "COVID-19". Thank you! ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:47:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 18:04:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 18:04:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 17:49:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 17:49:30
Data point term sent to Coder	System	01 Feb 2021 17:48:17
Query 'Please update term to "COVID-19". Thank you! ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	01 Feb 2021 17:48:01
Coding entries removed.	(b) (4) Heather Douds (b) (4)	01 Feb 2021 17:47:52
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	01 Feb 2021 17:47:52
User opened query 'Please update term to "COVID-19". Thank you! ' (Site from CRA).	(b) (4), (b) (6)	30 Jan 2021 23:04:09

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 15:34:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 15:34:02
Data point term sent to Coder	System	27 Jan 2021 15:33:01
User entered 'COVID19'	Cassandra Zehenny (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '18 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:47:52
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '31 Jan 2021' reason for change: New Information	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:47:52
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Feb 2021 17:47:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:48:00
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Jan 2021 15:32:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:15:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	27 Jan 2021 15:32:37

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Stanley Dublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 14:59:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 14:59:05
Data point term sent to Coder	System	31 Mar 2021 14:58:20
User entered 'worsening hypertension'	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Yes (Y)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '29 Mar 2021'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Yes (Y)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:09
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 15:05:02
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	09 Apr 2021 15:05:02
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 15:05:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
	(b) (4)	
User entered '0'	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:23
User closed query 'Per source, action taken - concomitant medication, not procedure. Please reconcile .' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:53:55
Query 'Per source, action taken - concomitant medication, not procedure. Please reconcile .' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:13
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:02
Signature has been broken.	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:02
User entered '0' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:05:02
User opened query 'Per source, action taken - concomitant medication, not procedure. Please reconcile .' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:30:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:12:34
User entered '1'	Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	29 Mar 2021 17:17:32

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	31 Mar 2021 14:57:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Dublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 14:57:39
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 17:17:32
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Stanley Dublin (b) (4)	31 Mar 2021 14:56:19
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	29 Mar 2021 17:17:32

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 15:00:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 15:00:10
Data point term sent to Coder	System	31 Mar 2021 14:59:23
User entered 'EPISTAXIS' reason for change: Data Entry Error	Stanley Doublin (b) (4)	31 Mar 2021 14:59:00
User entered 'epitaxis'	Stanley Doublin (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 14:58:30

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Mar 2021 14:58:30

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 22:01:17
User entered 'USA-US089-2021-mRNA-1273-P301000008'	System	07 Apr 2021 22:00:48
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 22:00:48

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:37:40
Data point term sent to Coder	System	07 Apr 2021 15:36:52
User entered 'congestive heart failure'	Heather Douds (b) (4)	07 Apr 2021 15:35:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '4 Apr 2021'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:01:26
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
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	07 Apr 2021 15:36:16
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	07 Apr 2021 15:35:54
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Apr 2021 14:05:04
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 Apr 2021 14:05:04
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	12 Apr 2021 14:04:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 09:58:30
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated; patient is still in the hospital at this time. Will add discharge date upon discharge.' (Site from System).	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:36:45
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 15:36:16
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	07 Apr 2021 15:36:16

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered '1' reason for change: Data Entry Error	System Heather Douds (b) (4)	07 Apr 2021 15:36:16 07 Apr 2021 15:36:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System Heather Douds (b) (4)	07 Apr 2021 15:35:54 07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:39:08
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:17:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'We are still awaiting medical records at this time and will update the narrative with any COVID-19 testing information that is provided once said records are available' (Site from Safety).	Heather Douds (b) (4) (b) (4)	16 Apr 2021 13:54:55
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:01:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:09:51
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 14:05:04
User entered '05 Apr 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 14:05:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '5 Apr 2021'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:17:33
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:17:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'We are still awaiting medical records at this time and will update narrative and provide said records to medical monitor once they are available, thank you' (Site from Safety).	Heather Douds (b) (4) (b) (4)	16 Apr 2021 13:54:14
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'hospital discharge date has been entered' (Site from Safety).	Heather Douds (b) (4) (b) (4)	16 Apr 2021 13:52:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:02:48
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:09:52
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 14:05:04

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Apr 2021' reason for change: New Information DataPoint Verified.	Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6)	12 Apr 2021 14:05:04 08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether the subject required an ICU visit.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:17:53
Query 'PV Query: Please clarify whether the subject required an ICU visit.' answered with 'Please note that "no" has been selected' (Site from Safety).	Heather Douds (b) (4)	16 Apr 2021 13:52:49
User opened query 'PV Query: Please clarify whether the subject required an ICU visit.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:00:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:09:54
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	12 Apr 2021 14:04:40
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 by data change (Site from System).		12 Apr 2021 14:04:40
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	12 Apr 2021 14:04:40
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Apr 2021 14:04:40
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
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	07 Apr 2021 15:35:54
User entered 'Unknown (UNK)'	Heather Douds (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:39:52
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:18:00
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'We are still awaiting medical records and will update both con medications and narrative when they are available, thank you' (Site from Safety).	Heather Douds (b) (4) (b) (4)	16 Apr 2021 13:53:16
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:01:59
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'I'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:01:46
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV: Query: Narrative said that subject was found to have pneumonia. Please clarify if this should be a separate AE,' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:40:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:40:14
User closed query 'PV: Query: Narrative said that subject was found to have pneumonia. Please clarify if this should be a separate AE,' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:18:04
Query 'PV: Query: Narrative said that subject was found to have pneumonia. Please clarify if this should be a separate AE,' answered with 'We are still awaiting medical records at this time and will update AEs, con medications, and narrative once additional information is available' (Site from Safety).	Heather Douds (b) (4) (b) (4)	16 Apr 2021 13:53:46
User opened query 'PV: Query: Narrative said that subject was found to have pneumonia. Please clarify if this should be a separate AE,' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 07:00:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Subject was at a local park with family over the weekend; family noticed on Sunday that he looked unwell. Subject reported having shortness of breath and a cough that started Sunday, was admitted to the hospital on Monday for congestive heart failure and also found to have pneumonia. Subject currently still inpatient; will send medical records once he has been discharged.'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:35:54

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 15:35:54

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
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)	07 Apr 2021 15:38:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 15:38:45
Data point term sent to Coder	System	07 Apr 2021 15:37:58
User entered 'pneumonia'	Heather Douds (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '5 Apr 2021'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:37:18

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'I'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered '0'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:25:09
User entered empty.	Heather Douds (b) (4) (b) (4)	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 15:37:18

US3552232

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:15:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:37:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:15:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Aug 2020 20:27:10
User entered 'Lantus' reason for change: Data Entry	Mikayla Frye (b) (4)	29 Aug 2020 20:26:51
Error	(b) (4)	
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	13 Oct 2020 13:53:28
User entered 'type 1 diabetes'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '25' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:16:06
User entered '30'	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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Please add meds administered during hospitalization (PCR notes page 19). ' (Site from CRA).	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	13 Oct 2020 13:53:54
User entered 'type 1 diabetes'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Please capture procedures performed during hospitalization , inclusive of CT chest, CXR (26Sep and 06Oct), bronchoscopy ' (Site from CRA).	(b) (4) (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) (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) (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) (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) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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)'	(b) (4)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:04:14
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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.	(b) (4) 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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User entered 'I'	System	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
User entered 'I'	System	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:18
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:22:27
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 20:28:39
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 20:28:39
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	29 Mar 2021 20:28:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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 19:04:45
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:22:29
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
DataPoint Un-verified.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:28:39
Signature has been broken.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:28:39
User entered '29 Mar 2021' reason for change: New Information	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:28:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User entered 'l'	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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
User entered 'l'	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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:22
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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.	Coder Import (b) (4) (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) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
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) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
User entered '15 Oct 2020' reason for change: New Information	(b) (4) Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User entered 'I'	System	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
User entered 'I'	System	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:33
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	System	13 Oct 2020 13:56:31
Coding entries removed.	Heather Douds (b) (4) (b) (4)	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	System	29 Aug 2020 19:07:11
User entered 'metformin'	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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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)'	(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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
User entered 'I'	System	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:37:38
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:14
DataPoint Un-verified.	Heather Douds (b) (4)	20 Jan 2021 15:44:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	20 Jan 2021 15:44:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Aug 2020 19:08:22
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:16
DataPoint Un-verified.	Heather Douds (b) (4)	20 Jan 2021 15:44:58
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 15:44:58
DataPoint Verified.	Heather Douds (b) (4)	14 Oct 2020 16:06:12
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:08:22
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User entered 'I'	System	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
User entered 'I'	System	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:04
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 04:08:40
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:20:24
' answered with 'per subject, taken for seasonal allergies, as in medical history' (Site from DM). 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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	18 Jan 2021 18:43:05
' (Site from DM). 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Cassandra Zehenny (b) (4)	21 Oct 2020 14:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	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
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 Dublin (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	Cassandra Zehenny (b) (4)	21 Oct 2020 14:26:03
DataPoint Verified.	(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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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) (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 'I'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'as needed (PRN)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '22 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)'	(b) (4) 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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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.	(b) (4) 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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:09
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
Query 'Please check spelling - Amniodarone' canceled (Site from CRA).	(b) (4)	
User opened query 'Please check spelling - Amniodarone' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:27:41
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.	(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
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per source, start date - 06Oct. Please reconcile ' (Site from CRA).	(b) (4) (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) (b) (4)	28 Oct 2020 18:39:57
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:39:53
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:39:53
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
User entered '8 Oct 2020'	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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:47:38
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'maintenance to prevent recurrence, data correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:20:45
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 17:15:49
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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:10:09
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:15
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'maintenance to prevent recurrence, correct as entered' (Site from DM). User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	21 Jan 2021 05:47:47 19 Jan 2021 19:21:09 18 Jan 2021 17:18:20 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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:37:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:37:11
Data point term sent to Coder	System	15 Dec 2020 19:20:12
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:19:53
User closed query 'Per MM: The same subject received another course of prednisone in the subsequent row. Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:59:48
Query 'Per MM: The same subject received another course of prednisone in the subsequent row. Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' ' answered with 'Subject did not receive second vaccination, therefore not relevant exclusion criteria' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Dec 2020 16:30:58

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per MM: The same subject received another course of prednisone in the subsequent row. Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids <u>></u> 20 mg/day of prednisone equivalent). ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 10:18:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (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) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 19:05:52
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:19:53
	(b) (4)	
User entered 'PNEUMONIA, respiratory failure'	Heather Douds (b) (4)	15 Dec 2020 19:19:53
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Pneumonia'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '40'	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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	11 Nov 2020 17:15:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:46:37
DataPoint Verified.	Mikayla Frye (b) (4)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	(b) (4), (b) (6)	
	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User entered 'I'	System	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
User entered 'I'	System	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:19
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (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) (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) (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) (b) (4)	12 Nov 2020 21:29:39
Coding entries removed.	Cassandra Zehenny (b) (4) (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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:25:23
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 21:25:23
Data point term sent to Coder	System	12 Oct 2020 21:24:12
User entered 'Metoprolol XL'	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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:57:53
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	12 Nov 2020 21:29:11
User entered 'Atrial Fibrillation' reason for change:	Cassandra Zehenny (b) (4)	12 Nov 2020 21:29:11
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Hypertension'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:10:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:30
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:30
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:48:08
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'maintenance to prevent recurrence; correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:21:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:49:32
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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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 DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM). 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 DEPRESSION should be recorded, and update con med indication or provide clarification. ' answered with 'AE not required' (Site from DM). 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 DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	21 Jan 2021 05:49:03 19 Jan 2021 19:21:42 18 Jan 2021 18:54:41
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)	14 Oct 2020 16:06:12 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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:10:22
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:36
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	11 Nov 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'non-st elevated myocardial infarction'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '324'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:28
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	15 Dec 2020 21:22:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 21:22:01
Data point term sent to Coder	System	15 Dec 2020 19:21:16
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:20:33
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:06:13
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:20:33
User entered 'PNEUMONIA, respiratory failure'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	15 Dec 2020 19:20:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4)	19 Oct 2020 14:53:25
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2000'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User entered 'I'	System	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
User entered 'I'	System	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:38:56
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	15 Dec 2020 22:06:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 22:06:58
Data point term sent to Coder	System	15 Dec 2020 19:21:16
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:20:40
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:06:20
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:20:40
User entered 'PNEUMONIA, respiratory failure'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	15 Dec 2020 19:20:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Dublin (b) (4)	19 Oct 2020 14:54:22
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '250'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Dublin (b) (4) (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 Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
User entered 'l'	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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:01
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	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 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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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
User entered 'hypomeynesia'	Stanley Doublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'g (g)'	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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:11
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5/325'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'as needed (PRN)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:53
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:15
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'nausea'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '4'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:39
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	20 Jan 2021 00:24:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:24:11
Data point term sent to Coder	System	19 Jan 2021 19:23:01
Coding entries removed.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:22:08
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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
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). Data point term sent to Coder Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 12 Nov 2020 21:30:19
	System	12 Nov 2020 21:30:15
	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
	(b) (4)	
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). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Nov 2020 18:23:16
	(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 15:00:45
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.' answered with 'data correct as entered' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:02:35
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.'	Heather Douds (b) (4)	19 Jan 2021 19:22:28
answered with 'data correct as entered' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:39:50
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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'coronary artery disease'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '80'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:06:36
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:51:16
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'data entry error; updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:22:16
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:22:08
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:22:08
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:40:14
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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User entered 'I'	System	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
User entered 'I'	System	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:47
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 Dublin (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 04:12:03
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'please see AEs related to pneumonia, data correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:23:06
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 05:12:04
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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '200'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'as needed (PRN)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:51
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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 TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:51:41
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 TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:23:27
' answered with 'AE not required' (Site from DM). 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 TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:59:28
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 Dublin (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'type 2 diabetes'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'units'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:06
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:39:56
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #18 ASPIRIN / (UNK2013-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:16:55
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)	20 Jan 2021 15:45:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:45:05
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #18 ASPIRIN / (UNK2013-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' answered with 'updated end dates based on medical records' (Site from DM).	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:23
Data point term sent to Coder	System	20 Jan 2021 15:44:20
Coding entries removed.	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:10
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #18 ASPIRIN / (UNK2013-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 17:23:55
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 (27)

Generated On: 10 Jun 2021 08:15:12

[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: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (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)	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)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:06:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:13:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:27
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:10
User entered 'coronary artery disease' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:10
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 17:23:33
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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '81'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:00
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	20 Jan 2021 15:44:10
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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 19:07:02
DataPoint Un-verified.	Heather Douds (b) (4)	20 Jan 2021 15:44:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	20 Jan 2021 15:44:10
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
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:15:12

[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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
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: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 10:58:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 10:58:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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)	17 Dec 2020 18:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:17:45
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	15 Dec 2020 19:21:14 15 Dec 2020 19:21:13
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 (28)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	02 Feb 2021 19:07:08
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:07:08
	Heather Douds (b) (4)	15 Dec 2020 19:21:13
	(b) (4)	15 Dec 2020 19:21:13
User entered 'PNEUMONIA, respiratory failure'	Heather Douds (b) (4)	15 Dec 2020 19:21:13
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered '6'	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Doublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:08:23
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	28 Oct 2020 18:58:45
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	Stanley Dublin (b) (4)	19 Oct 2020 15:08:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User entered 'I'	System	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
User entered 'I'	System	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:27:27
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	18 Dec 2020 00:46:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:46:53
Data point term sent to Coder	System	15 Dec 2020 19:22:19
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:21:33
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:13
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:21:33
User entered 'PNEUMONIA, respiratory failure'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	15 Dec 2020 19:21:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Dublin (b) (4)	19 Oct 2020 15:09:29
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '750'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:08
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30/600'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:31
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
User entered 'I'	System	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:13
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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 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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'bronchoscopy'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2.5'	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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Oct 2020 18:40:20
User entered 'Other (OTHER)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 05:48:40
	(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	(b) (4)	
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 18:40:20
User entered 'inhalation'	(b) (4), (b) (6)	28 Oct 2020 13:52:40
	Stanley Doublin (b) (4)	19 Oct 2020 15:14:01
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:19
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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 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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'bronchoscopy'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1.5'	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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mL (mL)'	Stanley Doublin (b) (4)	19 Oct 2020 15:15:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Oct 2020 18:40:42
User entered 'Other (OTHER)'	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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 05:48:47
	(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	(b) (4)	
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 18:40:42
User entered 'inhalation'	(b) (4), (b) (6)	28 Oct 2020 13:53:17
	Stanley Doublin (b) (4)	19 Oct 2020 15:15:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:24
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
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)	05 Mar 2021 03:03:53
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 'Not an AE' (Site from DM).	Heather Douds (b) (4) (b) (4)	04 Mar 2021 14:52:32
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)	04 Mar 2021 08:02:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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 Jan 2021 19:27:08
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 Jan 2021 19:27:08
Data point term sent to Coder	System	19 Jan 2021 19:26:04
Coding entries removed.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:13
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 (33)

Generated On: 10 Jun 2021 08:15:12

[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)	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)	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)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR RQ: Response Noted. However, the MH #2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:03:48
Query 'Per DM CLR RQ: Response Noted. However, the MH #2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'med history is ongoing. ended in error and corrected. thank you' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	22 Jan 2021 16:49:49
User opened query 'Per DM CLR RQ: Response Noted. However, the MH #2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 04:02:03
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 04:02:03
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'please see MH #2' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:03
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:46:07
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'coronary artery disease'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '40'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:30
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:52:47
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'data entry error' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:21
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:13
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:13
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:47:10
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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered '2 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User entered 'I'	System	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
User entered 'I'	System	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:41:28
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
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)	18 Dec 2020 00:46:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:46:05
Data point term sent to Coder	System	15 Dec 2020 19:22:21
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:21:57
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)	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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:15:12

[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)	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)	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)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:50
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:21:57
User entered 'PNEUMONIA, respiratory failure'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	15 Dec 2020 19:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '.63'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 houthd'	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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Oct 2020 18:41:12
User entered 'Other (OTHER)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 05:48:59
	(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	(b) (4)	
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
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered '2 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:02
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med# 42 / (15Oct2020-15Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 04:03:14
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med# 42 / (15Oct2020-15Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'please see doses' (Site from DM).	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:25:45
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med# 42 / (15Oct2020-15Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:49:29
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: BENZOTHAZEPINE 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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:07
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '.5'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:11:21
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data Entry Error	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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
	(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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:12
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '150'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:05
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:18
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '450'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'continuous'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
	(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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '6 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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:23
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
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) (4), (b) (6)	21 Jan 2021 05:53:05
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.	Heather Douds (b) (4) (b) (4)	19 Jan 2021 19:26:07
' answered with 'AE not required' (Site from DM). 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)	19 Jan 2021 04:29:10
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '20'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:57
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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	(b) (4) 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
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) Heather Douds (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
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:02
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: 10 Jun 2021 08:15:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:37:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:37:12
Data point term sent to Coder	System	15 Dec 2020 19:23:21
Coding entries removed.	Heather Douds (b) (4) (b) (4)	15 Dec 2020 19:22:26
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (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) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:34
DataPoint Un-verified.	Heather Douds (b) (4)	15 Dec 2020 19:22:26
User entered 'PNEUMONIA, respiratory failure'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	15 Dec 2020 19:22:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	26 Oct 2020 12:55:28
User entered 'Yes (Y)'	(b) (4) 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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '24 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	26 Oct 2020 12:55:28
User entered empty.	(b) (4) 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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User entered 'I'	System	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
User entered 'I'	System	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:09
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:13
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:18
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:43:57
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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)	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)	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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:01
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 04:38:34
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/medical diagnosis that this medication is preventing. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:37:30
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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User closed query 'Per DM CLR RQ: Response noted. However, the MH#2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4)	
Query 'Per DM CLR RQ: Response noted. However, the MH#2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'med history is ongoing. ended in error and corrected. thank you' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:04:15
Query 'Per DM CLR RQ: Response noted. However, the MH#2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'med history is ongoing. ended in error and corrected. thank you' (Site from DM).	Cassandra Zehenny (b) (4)	22 Jan 2021 16:50:11
User opened query 'Per DM CLR RQ: Response noted. However, the MH#2 is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 04:04:36
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 04:04:36
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'please see medical history #2' (Site from DM).	Heather Douds (b) (4)	19 Jan 2021 19:24:44
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:48:39
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 (46)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
User entered 'I'	System	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:08
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
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: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
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: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:12
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: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
Query 'Please update conmed log to reflect all meds given during hospitalon on 15-17Oct. Thank you! ' canceled (Site from CRA).	(b) (4) (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: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '20'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '25 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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.	(b) (4) Heather Douds (b) (4)	04 Nov 2020 17:26:16
User entered '1 Nov 2020' reason for change: New Information	(b) (4) 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) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User entered 'I'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User entered 'I'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:28
User entered '804 (804)'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:03:51
Data point term sent to Coder	System	22 Dec 2020 18:03:07
User entered 'influenza vaccine'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'influenza prophylaxis'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'Other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'injection'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'once (ONCE)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered empty.	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'Intramuscular (INTRAMUSCULAR)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered empty.	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered '14 Dec 2020'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered '0'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered '14 Dec 2020'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:09:23
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User entered empty.	System	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User entered empty.	System	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:33
User entered empty.	System	22 Dec 2020 18:02:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:36
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 HBP COUGH & COLD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 08:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 08:24:45
Data point term sent to Coder	System	01 Feb 2021 16:56:13
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	01 Feb 2021 16:55:17
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)	28 Jan 2021 16:29:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 16:29:20
Data point term sent to Coder	System	27 Jan 2021 15:35:02
Data point term sent to Coder	System	26 Jan 2021 19:25:12
Coding entries removed.	Heather Douds (b) (4) (b) (4)	26 Jan 2021 19:24:13

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[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)	22 Jan 2021 18:29:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 18:29:04
Data point term sent to Coder	System	22 Jan 2021 15:54:41
User entered 'coricidin [Chlorpheniramine maleate/Dextromethorphan hydrobromide]'	Stanley Doublin (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:38
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:39
User entered 'COVID-19' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	01 Feb 2021 16:55:17
User entered 'COVID19' reason for change: New Information	Cassandra Zehenny (b) (4)	27 Jan 2021 15:34:47
User entered 'nasal congestion, rhinorrhea' reason for change: Data Entry Error	Heather Douds (b) (4)	26 Jan 2021 19:24:13
User entered 'viral rhinitis'	Stanley Dublin (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:41
User entered '4/30'	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:43
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:15
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:17
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:19
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:21
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:23
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:25
User entered '18 Jan 2021'	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:27
User entered '0'	Stanley Doublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:12
User closed query 'Is this still ongoing, covid19 symptoms ended 31Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:17:09
Query 'Is this still ongoing, covid19 symptoms ended 31Jan2021. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 16:07:41
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 16:07:36
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:51:29
User opened query 'Is this still ongoing, covid19 symptoms ended 31Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:50:32
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User closed query 'Per ETRTR: covid-19 symptoms ended on 31Jan2021. Please confirm if the subject received conmed a day later?' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 16:30:29
Query 'Per ETRTR: covid-19 symptoms ended on 31Jan2021. Please confirm if the subject received conmed a day later?' answered with 'as reported by subject' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	23 Feb 2021 19:34:08
User opened query 'Per ETRTR: covid-19 symptoms ended on 31Jan2021. Please confirm if the subject received conmed a day later?' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:19:55
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:17:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 16:07:36
User entered '01 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:51:30
User entered empty.	Stanley Dublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:32
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User entered '2'	System	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User entered 'I'	System	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:44:38
User entered '804 (804)'	System	22 Jan 2021 15:54:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:49:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:49:57
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
Data point term sent to Coder	(b) (4) System	22 Feb 2021 19:40:05
User entered 'tylenol #3'	Stanley Dublin (b) (4)	22 Feb 2021 19:40:00
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:21
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication. Please update response to "No" if applicable. Ensure to add a medical condition that matches this Con Med indication that is used within this timeframe on MH or AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication. Please update response to "No" if applicable. Ensure to add a medical condition that matches this Con Med indication that is used within this timeframe on MH or AE eCRF as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4) (b) (4) Cassandra Zehenny (b) (4) (b) (4) Cassandra Zehenny (b) (4)	12 Mar 2021 03:02:08 10 Mar 2021 17:40:31 10 Mar 2021 17:40:22
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:22
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication. Please update response to "No" if applicable. Ensure to add a medical condition that matches this Con Med indication that is used within this timeframe on MH or AE eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4) (b) (4), (b) (6) sharon frey (b) (4)	10 Mar 2021 11:17:34 26 Feb 2021 03:22:31
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'back pain'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:21
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 02:57:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:41
Signature has been broken.	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:22
User entered '500' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:17:15
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '1'	(b) (4) Stanley Doublin (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:31:21
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:22
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Mar 2021 17:40:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
	(b) (4)	
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4)	22 Feb 2021 19:40:00
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'as needed (PRN)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'un Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	01 Apr 2021 17:01:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	01 Apr 2021 17:01:14
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:22:31
	(b) (4)	
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	22 Feb 2021 19:40:00
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:12:34
Signature has been broken.	(b) (4)	
	Stanley Doublin (b) (4)	01 Apr 2021 17:01:14
	(b) (4)	
User entered '29 Mar 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4)	01 Apr 2021 17:01:14
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	26 Feb 2021 03:22:31
	(b) (4)	
User entered empty.	Stanley Doublin (b) (4)	22 Feb 2021 19:40:00
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:23:29
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:22:31
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:40:00

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
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.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 20:30:59
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 Mar 2021 20:30:59
Data point term sent to Coder	System	29 Mar 2021 20:29:27
User entered 'Hydralazine'	Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'hypertension'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '75'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'three times daily (TID)'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '29 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:45:47
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:15:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 20:29:25

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:15:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:16
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:16:44
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:16:37
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: 10 Jun 2021 08:15:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:16
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:16:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:16:37
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) (b) (4)	13 Oct 2020 15:38:26
User entered 'SAE (specify) (SAE)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (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) (b) (4)	08 Oct 2020 13:02:25

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:16
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:20:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:16:47
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:16:37
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

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:15:12

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

Audit	User	Time (GMT)
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
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).	Cassandra Zehenny (b) (4)	13 Oct 2020 15:39:20
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).	(b) (4), (b) (6)	13 Oct 2020 02:39:27
User entered 'Pneumonia, respiratory failure'	Heather Douds (b) (4)	08 Oct 2020 13:02:25

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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.	(b) (4)	
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
	(b) (4)	

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:46:10
User entered 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:48
User entered 'l'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:55:34
User entered 'I'	(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: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	09 Nov 2020 16:38:30

US3552232

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
	(b) (4)	
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: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:55:40
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 14:17:31

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'USA-US089-2021-MRNA-1273-P301000002'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'sharon'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'frey'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:44
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '1100 S. Grand Blvd'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:45
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'St. Louis'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'MO'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:47
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '63122'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
User entered 'US'	System	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'I'	(b) (4) System	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'USA-US089-2021-MRNA-1273-P301000002'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'No (N)'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'sharon'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'frey'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:44
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '1100 S. Grand Blvd'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:45
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered 'St. Louis'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 18:32:33
User entered 'MO'	System	02 Feb 2021 18:32:07

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:47
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Signature has been broken.	(b) (4)	07 Apr 2021 22:00:48
User entered empty.	System	07 Apr 2021 22:00:48
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:26:35
User entered '63122'	(b) (4)	29 Mar 2021 17:17:11
	Heather Douds (b) (4)	
	(b) (4)	

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
User entered 'US'	System	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
User entered 'I'	(b) (4) System	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Feb 2021 18:47:13
User entered '02/Feb/2021 13:32'	System	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:20:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:47:13
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 18:32:47

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'USA-US089-2021-MRNA-1273-P301000008'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'sharon'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'frey'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:54
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:06
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:56
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:08
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'MO'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:57
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:10
User entered '63104'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
User entered 'US'	(b) (4) System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:17:03
User entered '1'	System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'USA-US089-2021-MRNA-1273-P301000008'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'sharon'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'frey'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:54
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:06
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:56
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:08
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'MO'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:57
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:10
User entered '63104'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
User entered 'US'	(b) (4) System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:17:03
User entered '1'	System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
User entered '07/Apr/2021 18:37'	(b) (4) System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'USA-US089-2021-MRNA-1273-P301000008'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'Yes (Y)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'No (N)'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'sharon'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'frey'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:54
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:06
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:56
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:08
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:37:10
User entered 'MO'	System	07 Apr 2021 22:00:48

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:57
DataPoint Un-verified.	System	13 Apr 2021 13:17:03
User entered empty.	System	13 Apr 2021 13:17:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:10:10
User entered '63104'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 15:04:46

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:37
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:27:36
User entered 'US'	(b) (4) System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:17:03
User entered '1'	System	07 Apr 2021 22:37:24

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:15:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	14 Apr 2021 15:24:02
User entered '13/Apr/2021 06:16'	System	13 Apr 2021 13:17:03

US3552232

Folder: SAE USA-US089-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:15:12

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:24:02
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:17:03