

US3582102 (Prod: Kaiser Permanente - Seattle)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:17:16

All time stamps listed in this document are displayed in GMT

US3582102

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 00:00:15

Generated On: 10 Jun 2021 08:17:16

[Participant ID](#)

US3582102

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

US3582102

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:00:27

Generated On: 10 Jun 2021 08:17:16

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
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	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:00:27

Generated On: 10 Jun 2021 08:17:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	3 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:00:27

Generated On: 10 Jun 2021 08:17:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:00:27

Generated On: 10 Jun 2021 08:17:16

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	18 OCT 2004
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)	OCT 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3582102

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	ATRIAL FLUTTER/ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	15 OCT 2004
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)	OCT 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3582102

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	14 NOV 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)	NOV 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	ATRIAL SEPTAL DEFECT
Start date (dd MMM yyyy)	UN UNK 1983
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 DEC 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	DEC 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	VENTRICULAR SEPTAL DEFECT
Start date (dd MMM yyyy)	UN DEC 2011
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)	DEC 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	16 FEB 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)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	THYROID NODULES
Start date (dd MMM yyyy)	06 MAR 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)	MAR 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) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	THYROMEGALY
Start date (dd MMM yyyy)	28 OCT 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)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3582102

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	PULMONARY NODULE
Start date (dd MMM yyyy)	06 MAR 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)	MAR 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	13 MAY 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	MAY 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) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	HEART FAILURE
Start date (dd MMM yyyy)	14 DEC 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)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	BARRETT'S ESOPHAGUS
Start date (dd MMM yyyy)	09 MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	OPEN ANGLE GLAUCOMA
Start date (dd MMM yyyy)	01 OCT 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	COLON POLYPS
Start date (dd MMM yyyy)	09 MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	MILD PULMONARY HYPERTENSION
Start date (dd MMM yyyy)	13 FEB 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)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	MODERATE MITRAL REGURGITATION
Start date (dd MMM yyyy)	13 FEB 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)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	SEBORRHEIC DERMATITIS
Start date (dd MMM yyyy)	16 JUL 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)	JUL 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	CYST ON BUTTOCK
Start date (dd MMM yyyy)	23 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	14 DEC 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)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	REFLUX
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	24 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	ANEMIA
Start date (dd MMM yyyy)	21 MAR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 26 Mar 2021 19:29:44

Generated On: 10 Jun 2021 08:17:16

Condition	STOMACH POLYP
Start date (dd MMM yyyy)	02 MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:02
Height (xxx.x)	68.8 in
Weight (xxx.x)	183.6 lb
BMI (xxx.x)	27.32786 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 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) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:00:28

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	WEEKLY TRIPS TO GROCERY STORE, WIFE 2X A WEEK FOR GROCERIES, GOLFS REGULARLY IN A GOLFING LEAGUE. WIFE TO RESTAURANT FREQUENTLY.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189484

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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)	3 SEP 2020
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:02
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	47 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:45
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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.

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:09 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:09

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

US3582102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	3 SEP 2020 13:25

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:35	3 SEP 2020 13:35
Nasopharyngeal Swab 2	No		

US3582102

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:50

PC Open Date & Time

03 SEP 2020 14:29

PC Close Date & Time

03 SEP 2020 16:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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 97.4 °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	04 SEP 2020 06:33
PC Open Date & Time	03 SEP 2020 17:54
PC Close Date & Time	04 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 22:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:19

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:40

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

03 SEP 2020 14:51

PC Open Date & Time

03 SEP 2020 14:29

PC Close Date & Time

03 SEP 2020 16:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

04 SEP 2020 06:34

PC Open Date & Time

03 SEP 2020 17:54

PC Close Date & Time

04 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

04 SEP 2020 22:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

05 SEP 2020 21:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

06 SEP 2020 21:09

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

07 SEP 2020 21:19

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

08 SEP 2020 20:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

09 SEP 2020 19:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:51
PC Open Date & Time	03 SEP 2020 14:29
PC Close Date & Time	03 SEP 2020 16:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 06:35
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PC Open Date & Time	03 SEP 2020 17:54
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PC Close Date & Time	04 SEP 2020 11:59
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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:09
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

		Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 21:18	
PC Open Date & Time	05 SEP 2020 12:00	
PC Close Date & Time	06 SEP 2020 11:59	

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

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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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:10
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:29
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

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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US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:42
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3582102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT2

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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)	01 OCT 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 11:00
Temperature (xxx.x)	99 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:04
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3582102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 11:33

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

US3582102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	01 OCT 2020 11:18

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	01 OCT 2020 11:26
Nasopharyngeal Swab 2	No		

US3582102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:12

PC Open Date & Time

01 OCT 2020 11:53

PC Close Date & Time

01 OCT 2020 14:23

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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 97.3 °F

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

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

PC Time Stamp	02 OCT 2020 05:12
PC Open Date & Time	01 OCT 2020 15:18
PC Close Date & Time	02 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

03 OCT 2020 20:16

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

98.0 °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

04 OCT 2020 22:30

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:10

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

06 OCT 2020 20:16

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

97.6 °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

07 OCT 2020 18:42

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

01 OCT 2020 12:14

PC Open Date & Time

01 OCT 2020 11:53

PC Close Date & Time

01 OCT 2020 14:23

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

02 OCT 2020 05:09

PC Open Date & Time

01 OCT 2020 15:18

PC Close Date & Time

02 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

03 OCT 2020 20:17

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

04 OCT 2020 22:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

05 OCT 2020 19:10

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

06 OCT 2020 20:16

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

07 OCT 2020 18:42

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 12:15
PC Open Date & Time	01 OCT 2020 11:53
PC Close Date & Time	01 OCT 2020 14:23

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 05:12
PC Open Date & Time	01 OCT 2020 15:18
PC Close Date & Time	02 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:17
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

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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US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:32
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

119 of 2773

EAB) (1725)

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:11
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

121 of 2773

EAB) (1725)

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:17
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

123 of 2773

EAB) (1725)

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 18:43
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3582102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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)	13:34 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 13:34
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3582102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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.

US3582102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

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)	13:48 (24 HR)
Collection date and time (derived)	30 OCT 2020 13:48

US3582102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 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 NOV 2020 21:38:31
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 23:15:33

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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	17 NOV 2020 13:54:21
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 15:40:53

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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	28 NOV 2020 17:12:48
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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	05 DEC 2020 14:47:32
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

13 DEC 2020 11:27:11

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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	19 DEC 2020 16:20:11
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

26 DEC 2020 14:26:19

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 JAN 2021 19:23:49
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 20:24:31

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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	16 JAN 2021 13:15:37
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

23 JAN 2021 21:57:57

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

03 FEB 2021 15:00:58

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

07 FEB 2021 19:17:49

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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 FEB 2021 14:15:15
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 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	27 FEB 2021 23:22:50
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

08 MAR 2021 09:50:17

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

14 MAR 2021 19:08:59

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 18:50:50

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

28 MAR 2021 06:05:38

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 09:36:14

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

17 APR 2021 20:33:38

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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	25 APR 2021 13:46:15
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

01 MAY 2021 18:09:26

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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08 SEP 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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22 SEP 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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20 APR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

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23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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04 MAY 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

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14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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25 MAY 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Date and time of submission

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04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

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11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

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18 JUN 2022 00:01

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22 JUN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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13 JUL 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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20 JUL 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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03 AUG 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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10 AUG 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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24 AUG 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

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](#)

03 SEP 2022 00:01

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07 SEP 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Date and time of submission

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14 SEP 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 <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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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"/>

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3582102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:17:16

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		08 MAR 2021 09:50:51

US3582102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

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) _____

US3582102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

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.

US3582102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

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

Collection date (dd MMM yyyy)	16 MAR 2021
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Collection time (00:00-23:59)	13:45 (24 HR)
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Collection date and time (derived)	16 MAR 2021 13:45
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US3582102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3582102

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:17:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3582102

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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

Visit date (dd MMM yyyy)	13 JAN 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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US3582102

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3582102

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

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

US3582102

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

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 type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3582102

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

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)	14 JAN 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:45
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3582102

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3582102

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:14

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

US3582102

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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

Collection date (dd MMM yyyy)	13 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:21 (24 HR)
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Collection date and time (derived)	13 JAN 2021 13:21
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US3582102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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

US3582102

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:00:27

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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)	08 FEB 2021
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 09:44
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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)	08 FEB 2021
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 10:31
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3582102

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3582102

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:00:16

Generated On: 10 Jun 2021 08:17:16

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) 08 FEB 2021

What was the treatment time? (00:00-23:59) 10:01 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 10:01

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

US3582102

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3582102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:58:28

Generated On: 10 Jun 2021 08:17:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3582102

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

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) _____

US3582102

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

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.

US3582102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	16 MAR 2021 13:45

US3582102

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 00:00:15

Generated On: 10 Jun 2021 08:17:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

AEID	
Adverse event	CHIPPED TEETH
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)	12 DEC 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)	20 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

AEID

Adverse event

ANEMIA EXACERBATION

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 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

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)	_____

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

AEID	USA-US124-2021-MRNA-1273-P30 1000002
Adverse event	ACUTE LEFT MIDDLE CEREBRAL ARTERY STROKE
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)	21 FEB 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)	21 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	22 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

PARTICIPANT WOKE ON 2/21/21
WITH EXPRESSIVE AND
RECEPTIVE APHASIA. HE WAS
ADMITTED TO SWEDISH
HOSPITAL AND DIAGNOSED
WITH ACUTE LEFT MIDDLE
CEREBRAL ARTERY STROKE
WITH M3, M4 DISTRIBUTION
AND IMPROVING. PARTICIPANT
DISCHARGED ON 2/22/21 TO
HOME. STROKE THOUGHT TO
BE CARDIOEMBOLIC DUE TO
BEING OFF HIS WARFARIN FOR
HIS COLONOSCOPY AND
ENDOSCOPY ON 2/18/21.

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 (4)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

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	True
Concomitant Medication	False
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)	_____

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

AEID	
Adverse event	LACERATION TO GINGIVA
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)	12 DEC 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)	22 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 10 Apr 2021 18:30:49

Generated On: 10 Jun 2021 08:17:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 00:00:15

Generated On: 10 Jun 2021 08:17:16

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER AND
VENTRICULAR SEPTAL DEFECT

Dose per administration 7.5 OR 5

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

If dose unit is Other, specify 7.5MG M/W/F AND 5MG ALL
OTHER DAYS

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 (1)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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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)		15 NOV 2008
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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Name of Medication DIH-XR

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 120

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) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		09 APR 2005
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) 01 Apr 2021 21:58:16

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Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	14 DEC 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 (4)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication COZAAR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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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)		29 SEP 2009
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 (5)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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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)	07 APR 1997	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication XALATAN EYE DROPS .005%

Prophylaxis Yes ☐
No ☒

Indication OPEN ANGLE GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP BOTH EYES

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 (6)

Data signed: (b) (4) 01 Apr 2021 21:58:16

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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 checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	01 OCT 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 (7)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication HEART FAILURE

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 (7)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		14 DEC 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 (8)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication K-TAB

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MEQ

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) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	24 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 (9)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication PRILOSEC

Prophylaxis Yes ☐
No ☒

Indication REFLUX

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 (9)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 NOV 2003	
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) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication KETOCONAZOLE SHAMPOO 2%

Prophylaxis Yes ☐
No ☒

Indication SEBORRHEIC DERMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 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 checked="" 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 (11)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication CALCIUM WITH D3

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication PROSTATE PLUS HEALTH
COMPLEX: SAW PALMETTO,
ZINC GLUCONATE, PUMPKIN
SEED OIL, SUNFLOWER SEED
OIL

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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 checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication STIFFNESS IN BACK,
SHOULDERS, HIPS, KNEES

Dose per administration 400

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) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 UNK 1995	
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)		
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 (14)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

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 (14)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		31 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)		31 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 (15)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication CHIPPED TEETH AND
LACERATION TO GINGIVA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	15 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication CHLORHEXIDINE GLUCONATE
0.12%

Prophylaxis Yes ☐
No ☒

Indication CHIPPED TEETH AND
LACERATION TO GINGIVA

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 (16)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	ORAL RINSE (AND SPIT)	
Start date (dd MMM yyyy)	15 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)	22 DEC 2020	
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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication (IRON) FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	24 MAR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 DEC 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 (18)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication (IRON) FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ANEMIA EXACERBATION

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 (19)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		18 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANEMIA EXACERBATION

Dose per administration 3

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 (20)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	18 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication LIDOCAINE 4%

Prophylaxis Yes ☐
No ☒

Indication ANEMIA EXACERBATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		18 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER AND
VENTRICULAR SEPTAL DEFECT

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER,
VENTRICULAR SEPTAL
DEFECT, ACUTE LEFT MIDDLE
CEREBRAL ARTERY STROKE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 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"/>

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication POLYETHYLENE
GLYCOL-ELECTROLYTES
(GAVILYTE-C)

Prophylaxis Yes ☐
No ☒

Indication ANEMIA EXACERBATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication COUMADIN (WARFARIN)

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER/ATRIAL
FIBRILLATION, VENTRICULAR
SEPTAL DEFECT

Dose per administration 7.5 & 5.0

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

If dose unit is Other, specify 7.5MG - MONDAY,
WEDNESDAY, FRIDAY
5.0MG - TUESDAY, THURSDAY,
SATURDAY, SUNDAY

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

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

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

Name of Medication OMNIPAQUE 350 (IOHEXOL)

Prophylaxis Yes ☐
No ☒

Indication ACUTE LEFT MIDDLE
CEREBRAL ARTERY STROKE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 01 Apr 2021 21:58:16

Generated On: 10 Jun 2021 08:17:16

	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)		21 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 00:00:15

Generated On: 10 Jun 2021 08:17:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 DEC 2020	DENTAL BONDING OF 6 CHIPPED TEETH	Adverse Event	
29 DEC 2020	CT OF HEAD (DUE TO EXACERBATION OF ANEMIA)	Adverse Event	
18 FEB 2021	COLONOSCOPY	Adverse Event	
18 FEB 2021	UPPER ENDOSCOPY	Adverse Event	
21 FEB 2021	EKG	Adverse Event	
21 FEB 2021	CT HEAD WITHOUT CONTRAST	Adverse Event	
21 FEB 2021	CTA HEAD AND NECK	Adverse Event	
21 FEB 2021	CHEST X-RAY	Adverse Event	
21 FEB 2021	MRI BRAIN WITHOUT CONTRAST	Adverse Event	
23 FEB 2021	EKG	Adverse Event	
23 FEB 2021	EKG	Adverse Event	
24 FEB 2021	CT HEAD WITHOUT CONTRAST	Adverse Event	

US3582102

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:17:16

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3582102

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:17:16

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 ☐

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

SAEID	USA-US124-2021-MRNA-1273-P301000002
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	LISA
Investigator's Last Name	JACKSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

SAEID	USA-US124-2021-MRNA-1273-P301000002
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	LISA
Investigator's Last Name	JACKSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/FEB/2021 12:21
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

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 21:58:17

Generated On: 10 Jun 2021 08:17:16

SAEID	USA-US124-2021-MRNA-1273-P301000002
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	LISA
Investigator's Last Name	JACKSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/MAR/2021 13:36
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

US3582102 (Prod: Kaiser Permanente - Seattle)

US3582102

Form: Participant Creation

Generated On: 10 Jun 2021 08:17:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:40:39
User entered 'US3582102'	RWS_ENDPOINT	
	ENDPOINT (b) (4)	03 Sep 2020 18:59:31
	(b) (4)	

US3582102

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:39:54
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:24:51

US3582102

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:39:54
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 18:59:32

US3582102

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:39:54
User entered 'Clinic (Clinic)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:24:51

US3582102

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'SCRN'	System	08 Sep 2020 21:24:51

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 18:59:33

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '77'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'YEARS'	System	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '77'	System	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered 'Male (M)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered 'l'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered 'I'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:40:40
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:16

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered '3 Sep 2020'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Sep 2020'	System	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2020'	System	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 21:26:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 21:26:05
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:05
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 21:25:59
User entered empty.	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered 'Yes (Y)'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered empty.	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered empty.	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered 'No (N)'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:25:59

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:41:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 18:59:32

US3582102

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'l'	System	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:43:47
User entered 'Yes (Y)'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:17:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:04
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:25:50

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
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)	08 Sep 2020 21:26:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:26:55
Data point term sent to Coder	System	08 Sep 2020 21:26:11
User entered 'hypertension'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '18 Oct 2004'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Oct 2004'	System	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2004'	System	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:08

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4)	26 Mar 2021 19:29:44
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\23.0.	Coder Import (b) (4)	04 Mar 2021 22:19:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Mar 2021 22:19:40
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:58
Data point term sent to Coder	System	26 Feb 2021 19:21:44
DataPoint Un-verified.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:21:32
Coding entries removed.	(b) (4)	
	Marilyn Nguyen (b) (4)	26 Feb 2021 19:21:32
Signature has been broken.	(b) (4)	
	Marilyn Nguyen (b) (4)	26 Feb 2021 19:21:32
User entered 'ATRIAL FLUTTER/Atrial fibrillation' reason for change: New Information	(b) (4)	
User signature succeeded.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:21:32
	(b) (4)	
DataPoint Verified.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\23.0.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:27:55
Data point term sent to Coder	(b) (4)	
User entered 'atrial flutter'	Coder Import (b) (4)	08 Sep 2020 21:27:55
	(b) (4)	
	System	08 Sep 2020 21:27:14
	Barbara Carste (b) (4)	08 Sep 2020 21:26:22
	(b) (4)	

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '15 Oct 2004'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Oct 2004'	System	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2004'	System	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:22

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:27:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:27:55
Data point term sent to Coder	System	08 Sep 2020 21:27:14
User entered 'kidney stones'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'UN UNK 1985' reason for change:	Barbara Carste (b) (4)	08 Sep 2020 21:29:20
Data Entry Error	(b) (4)	
User entered 'UN UNK 1995'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jan 1985'	System	08 Sep 2020 21:29:20
User entered 'Jan 1995'	System	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '1985'	System	08 Sep 2020 21:29:20
User entered '1995'	System	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:26:51

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:27:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:27:55
Data point term sent to Coder	System	08 Sep 2020 21:27:14
User entered 'gastroesophageal reflux disease'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '14 Nov 2008'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Nov 2008'	System	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2008'	System	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:27:05

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Atrial septal defect, LLT: Atrial septal defect - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:28:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:28:56
Data point term sent to Coder	System	08 Sep 2020 21:28:22
User entered 'atrial septal defect'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'UN UNK 1983'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'un Dec 2011'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jan 1983'	System	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '1983'	System	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Dec 2011'	System	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2011'	System	08 Sep 2020 21:28:09

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Ventricular septal defect, LLT: Ventricular septal defect - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:29:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:29:57
Data point term sent to Coder	System	08 Sep 2020 21:29:25
User entered 'ventricular septal defect'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'un Dec 2011'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Dec 2011'	System	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2011'	System	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:28:49

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:31:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:31:41
Data point term sent to Coder	System	08 Sep 2020 21:30:30
User entered 'benign prostatic hyperplasia'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '16 Feb 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Feb 2015'	System	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:30:21

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:32:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:32:59
Data point term sent to Coder	System	08 Sep 2020 21:31:32
User entered 'thyroid nodules'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '06 Mar 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Mar 2015'	System	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:30:37

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Thyromegaly - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:38:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:38:01
Data point term sent to Coder	System	08 Sep 2020 21:36:42
User entered 'thyromegaly'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '28 Oct 2019'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Oct 2019'	System	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2019'	System	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:03

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:38:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:38:01
Data point term sent to Coder	System	08 Sep 2020 21:36:42
User entered 'pulmonary nodule'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '06 Mar 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Mar 2015'	System	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:19

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:02
Data point term sent to Coder	System	08 Sep 2020 21:37:44
User entered 'obstructive sleep apnea'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '13 May 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'l'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'May 2015'	System	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:36:51

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:01
Data point term sent to Coder	System	08 Sep 2020 21:37:44
User entered 'heart failure'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '14 Dec 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Dec 2015'	System	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:07

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:39:01
Data point term sent to Coder	System	08 Sep 2020 21:37:44
User entered 'barrett's esophagus'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '09 May 2017'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'May 2017'	System	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2017'	System	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:30

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Open angle glaucoma, LLT: Open angle glaucoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:40:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:40:00
Data point term sent to Coder	System	08 Sep 2020 21:38:45
User entered 'open angle glaucoma'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '01 Oct 2018'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Oct 2018'	System	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2018'	System	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:37:48

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:44:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:44:02
Data point term sent to Coder	System	08 Sep 2020 21:42:56
User entered 'colon polyps'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '09 May 2017'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'May 2017'	System	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2017'	System	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:42:33

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary hypertension, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:16:33
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 07:16:33
Data point term sent to Coder	System	08 Sep 2020 21:48:09
User entered 'MILD PULMONARY hyPERTENSION' reason for change: Data Entry Error	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:57
Data point term sent to Coder	System	08 Sep 2020 21:42:56
User entered 'mild pulmonary pertension'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '13 Feb 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Feb 2015'	System	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:42:54

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
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)	09 Sep 2020 07:16:33
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 07:16:33
Data point term sent to Coder	System	08 Sep 2020 21:43:57
User entered 'moderate mitral regurgitation'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '13 Feb 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Feb 2015'	System	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:43:16

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
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)	08 Sep 2020 21:47:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:02
Data point term sent to Coder	System	08 Sep 2020 21:46:05
User entered 'coronary artery disease'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Un UNK 2011'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jan 2011'	System	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2011'	System	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:20

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Seborrheic dermatitis, LLT: Seborrheic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:03
Data point term sent to Coder	System	08 Sep 2020 21:46:05
User entered 'seborrheic dermatitis'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '16 Jul 2013'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jul 2013'	System	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2013'	System	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:38

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Mass conditions NEC, PT: Cyst, LLT: Cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:42:41
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 07:42:41
Data point term sent to Coder	System	08 Sep 2020 21:46:06
User entered 'cyst on buttock'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '23 Jul 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jul 2020'	System	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2020'	System	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:45:54

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
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)	08 Sep 2020 21:47:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:52
Data point term sent to Coder	System	08 Sep 2020 21:47:07
User entered 'hyperlipidemia'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '14 Dec 2015'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Dec 2015'	System	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2015'	System	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:07

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 05:53:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 05:53:45
Data point term sent to Coder	System	08 Sep 2020 21:47:07
User entered 'reflux'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'un UNK 2003'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jan 2003'	System	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2003'	System	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:19

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:47:51
Data point term sent to Coder	System	08 Sep 2020 21:47:07
User entered 'hypokalemia'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '24 Feb 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Feb 2020'	System	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2020'	System	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:46:41

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue conditions NEC, PT: Musculoskeletal stiffness, LLT: Musculoskeletal stiffness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:41:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:41:45
Data point term sent to Coder	System	08 Sep 2020 21:48:08
User entered 'stiffness in back, shoulders, hips, knees'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Un UNK 1995'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:44:33
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Jan 1995'	System	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '1995'	System	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	08 Sep 2020 21:47:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 20:22:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 20:22:58
Data point term sent to Coder	System	15 Jan 2021 20:22:17
User entered 'anemia'	Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered '21 Mar 2017'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered '0'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:23:21
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered '0'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'Mar 2017'	System	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2017'	System	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	15 Jan 2021 20:21:30

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Gastric polyps, LLT: Gastric polyps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 06:56:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 06:56:09
Data point term sent to Coder	System	26 Feb 2021 19:20:43
User entered 'Stomach Polyp'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:51
User entered '02 May 2017'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:58
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:58
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:58
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	26 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:58
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'May 2017'	System	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '2017'	System	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	26 Feb 2021 19:20:39

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered '13:02'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '3 Sep 2020 13:02'	System	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered '68.8' in	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18
DataPoint set to visible.	System	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered '183.6' lb	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18
DataPoint set to visible.	System	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '27.32786'	System	08 Sep 2020 21:50:18
DataPoint set to visible.	System	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'kg/m2'	System	08 Sep 2020 21:50:18
DataPoint set to visible.	System	03 Sep 2020 21:26:15

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered 'Other (Other)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'bpm'	System	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'breaths/min'	System	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'mmHg'	System	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:51:50
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:27:56
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 22:27:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:27:56
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:50:18
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'mmHg'	System	11 Sep 2020 22:27:56
User entered empty.	System	08 Sep 2020 21:50:18

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09

US3582102

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09

US3582102

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:52:07
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:38

US3582102

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:52:07
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:50:38

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered '0'	(b) (4) Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'l'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered 'l'	(b) (4) Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:53:59
User entered 'weekly trips to grocery store, wife 2x a week for groceries, golfs regularly in a golfing league. wife to restaurant frequently.'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:51:58

US3582102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:07
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:09

US3582102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:07
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:09

US3582102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:07
User entered 'Clinic (Clinic)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:09

US3582102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'VISIT1'	System	08 Sep 2020 21:52:09

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 20:49:43

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered '189484'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 20:49:43

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 20:49:43

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

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)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:31

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

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)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:31

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:31

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:31

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:12
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:52:31

US3582102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:22:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. '(Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 07:28:38
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Confirmed and updated' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	17 Dec 2020 23:18:50
User entered 'No (N)'	Melissa Scheer (b) (4) (b) (4)	17 Dec 2020 23:18:42
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. '(Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:10:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:16:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:16:34

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Pre-Dose (PREDOSE)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '13:02'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '3 Sep 2020 13:02'	System	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '97.8' F	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered 'Other (Other)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered 'temporal'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '56'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'bpm'	System	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '20'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'breaths/min'	System	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '123'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
User closed query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 03:02:47
Query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'This is NCS. ' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	29 Oct 2020 00:00:43
User opened query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:16:43
User closed query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:16:43
Query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'Protocol states to use FDA grading scale, which does not have a lower limit for diastolic' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	22 Oct 2020 16:46:58
User opened query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:11:31
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 05:11:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Protocol states to use FDA grading scale, which does not have a lower limit for diastolic.' (Site from System). DataPoint Verified.	Barbara Carste (b) (4) (b) (4)	07 Oct 2020 05:53:57
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User entered '47'	(b) (4), (b) (6) System Barbara Carste (b) (4) (b) (4)	06 Oct 2020 18:54:48 17 Sep 2020 00:27:41 08 Sep 2020 21:53:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	08 Sep 2020 21:53:08

US3582102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered missing code ND - Not Done.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Post-Dose (POSTDOSE)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '14:45'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '3 Sep 2020 14:45'	System	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 22:26:45
User entered '97.5' F reason for change: Data Entry Error	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:26:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Sep 2020 21:53:40
User entered '97.5' (non-conformant).	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered 'Oral (Oral)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '50'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'bpm'	System	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '20'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'breaths/min'	System	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:54:48
User entered '118'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
User closed query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 03:02:58
Query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'This is NCS. ' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	29 Oct 2020 00:00:59
User opened query 'Per CDM ReQuery: Thank you for the response; however, please advise if Diastolic Blood pressure value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:17:18
User closed query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:17:18
Query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'Protocol states to use FDA grading scale, which does not have a lower limit for diastolic' (Site from DM).	Melissa Scheer (b) (4) (b) (4)	22 Oct 2020 16:47:26
User opened query 'Per CDM ReQuery: Thank you for the response; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:11:50
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 05:11:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Protocol states to use FDA grading scale, which does not have a lower limit for diastolic.' (Site from System). DataPoint Verified.	Barbara Carste (b) (4) (b) (4)	07 Oct 2020 05:54:05
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User entered '57'	(b) (4), (b) (6) System Barbara Carste (b) (4) (b) (4)	06 Oct 2020 18:54:48 17 Sep 2020 00:27:41 08 Sep 2020 21:53:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	08 Sep 2020 21:53:40

US3582102

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:00
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:47

US3582102

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:00
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:53:47

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered 'Yes (Y)'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered empty.	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

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)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered empty.	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered '3 Sep 2020'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered '14:09'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '3 Sep 2020 14:09'	System	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered 'Left Arm (LEFT ARM)'	Diana McFeters (b) (4) (b) (4)	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:12
User entered 'ONCE'	System	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 21:26:50

US3582102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:35
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:01

US3582102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:35
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:01

US3582102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:35
User entered '13:25'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:01

US3582102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '3 Sep 2020 13:25'	System	08 Sep 2020 21:54:01

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:41
User entered '3 Sep 2020'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:41
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:41
User entered '13:35'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '3 Sep 2020 13:35'	System	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:41
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:41
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered empty.	System	08 Sep 2020 21:54:14

US3582102

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:58:50
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 21:54:19

US3582102

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'I'	System	08 Sep 2020 21:54:19

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:48:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8b9f025a-2571-41ec-bc8b-6ca096b68eb2' User entered 'Yes (Y)'	System	03 Sep 2020 21:50:13
	System	03 Sep 2020 21:50:13

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:49:04', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8b9f025a-2571-41ec-bc8b-6ca096b68eb2' User entered '97.5'	System	03 Sep 2020 21:50:13
	System	03 Sep 2020 21:50:13

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:49:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8b9f025a-2571-41ec-bc8b-6ca096b68eb2' User entered 'No (N)'	System	03 Sep 2020 21:50:13
	System	03 Sep 2020 21:50:13

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:50:09', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8b9f025a-2571-41ec-bc8b-6ca096b68eb2' User entered '03 Sep 2020 14:50'	System	03 Sep 2020 21:50:13
	System	03 Sep 2020 21:50:13

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 14:29'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 16:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:32:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '55189125-d8f2-428a-b98a-aa705142c8ea' User entered 'Yes (Y)'	System	04 Sep 2020 13:33:21
	System	04 Sep 2020 13:33:21

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:32:59', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '55189125-d8f2-428a-b98a-aa705142c8ea' User entered '97.4'	System	04 Sep 2020 13:33:21
	System	04 Sep 2020 13:33:21

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:33:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '55189125-d8f2-428a-b98a-aa705142c8ea' User entered 'No (N)'	System	04 Sep 2020 13:33:21
	System	04 Sep 2020 13:33:21

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:33:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '55189125-d8f2-428a-b98a-aa705142c8ea' User entered '04 Sep 2020 06:33'	System	04 Sep 2020 13:33:21
	System	04 Sep 2020 13:33:21

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 17:54'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 2'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:06:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1926e2e8-eb3e-4182-a49d-102981d6f216' User entered 'Yes (Y)'	System	05 Sep 2020 05:07:28
	System	05 Sep 2020 05:07:28

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:07:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1926e2e8-eb3e-4182-a49d-102981d6f216' User entered '98.3'	System	05 Sep 2020 05:07:28
	System	05 Sep 2020 05:07:28

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:07:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1926e2e8-eb3e-4182-a49d-102981d6f216' User entered 'No (N)'	System	05 Sep 2020 05:07:28
	System	05 Sep 2020 05:07:28

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:07:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1926e2e8-eb3e-4182-a49d-102981d6f216' User entered '04 Sep 2020 22:07'	System	05 Sep 2020 05:07:28
	System	05 Sep 2020 05:07:28

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 3'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:16:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '080f5c3f-c95f-4eef-a21c-592c1fe17edf' User entered 'Yes (Y)'	System	06 Sep 2020 04:16:48
	System	06 Sep 2020 04:16:48

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:16:31', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '080f5c3f-c95f-4eef-a21c-592c1fe17edf' User entered '98.3'	System	06 Sep 2020 04:16:48
	System	06 Sep 2020 04:16:48

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:16:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '080f5c3f-c95f-4eef-a21c-592c1fe17edf' User entered 'No (N)'	System	06 Sep 2020 04:16:48
	System	06 Sep 2020 04:16:48

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:16:46', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '080f5c3f-c95f-4eef-a21c-592c1fe17edf' User entered '05 Sep 2020 21:16'	System	06 Sep 2020 04:16:48
	System	06 Sep 2020 04:16:48

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 4'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '39f70235-8b5a-4282-9dfe-231bbaee6107' User entered 'Yes (Y)'	System	07 Sep 2020 04:08:41
	System	07 Sep 2020 04:08:41

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '39f70235-8b5a-4282-9dfe-231bbaee6107' User entered '98.3'	System	07 Sep 2020 04:08:41
	System	07 Sep 2020 04:08:41

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:31', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '39f70235-8b5a-4282-9dfe-231bbaee6107'	System	07 Sep 2020 04:08:41
User entered 'No (N)'	System	07 Sep 2020 04:08:41

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '39f70235-8b5a-4282-9dfe-231bbaee6107' User entered '06 Sep 2020 21:08'	System	07 Sep 2020 04:08:41
	System	07 Sep 2020 04:08:41

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 5'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:18:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd66c242c-0fe9-4988-8c37-27ca16da448d' User entered 'Yes (Y)'	System	08 Sep 2020 04:19:06
	System	08 Sep 2020 04:19:06

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:18:47', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd66c242c-0fe9-4988-8c37-27ca16da448d' User entered '98.3'	System	08 Sep 2020 04:19:06
	System	08 Sep 2020 04:19:06

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:18:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd66c242c-0fe9-4988-8c37-27ca16da448d' User entered 'No (N)'	System	08 Sep 2020 04:19:06
	System	08 Sep 2020 04:19:06

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:00', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd66c242c-0fe9-4988-8c37-27ca16da448d' User entered '07 Sep 2020 21:19'	System	08 Sep 2020 04:19:06
	System	08 Sep 2020 04:19:06

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 6'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '07811f64-a616-4a71-882c-9eb9c853b8ca' User entered 'Yes (Y)'	System	09 Sep 2020 03:27:43
	System	09 Sep 2020 03:27:43

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:21', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '07811f64-a616-4a71-882c-9eb9c853b8ca' User entered '98.3'	System	09 Sep 2020 03:27:43
	System	09 Sep 2020 03:27:43

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:27', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '07811f64-a616-4a71-882c-9eb9c853b8ca' User entered 'No (N)'	System	09 Sep 2020 03:27:43
	System	09 Sep 2020 03:27:43

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '07811f64-a616-4a71-882c-9eb9c853b8ca' User entered '08 Sep 2020 20:27'	System	09 Sep 2020 03:27:43
	System	09 Sep 2020 03:27:43

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 7'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:40:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0569f50b-092d-4cab-bd88-e09110784bff' User entered 'Yes (Y)'	System	10 Sep 2020 02:40:58
	System	10 Sep 2020 02:40:58

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:40:41', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0569f50b-092d-4cab-bd88-e09110784bff' User entered '98.6'	System	10 Sep 2020 02:40:58
	System	10 Sep 2020 02:40:58

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:40:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0569f50b-092d-4cab-bd88-e09110784bff' User entered 'No (N)'	System	10 Sep 2020 02:40:58
	System	10 Sep 2020 02:40:58

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:40:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0569f50b-092d-4cab-bd88-e09110784bff' User entered '09 Sep 2020 19:40'	System	10 Sep 2020 02:40:58
	System	10 Sep 2020 02:40:58

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:50:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '73ffe50a-7e35-43ca-b1cb-23cf34912e33'	System	03 Sep 2020 21:51:13
User entered 'None (1)'	System	03 Sep 2020 21:51:13

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:50:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '73ffe50a-7e35-43ca-b1cb-23cf34912e33' User entered 'No (N)'	System	03 Sep 2020 21:51:13
	System	03 Sep 2020 21:51:13

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:50:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '73ffe50a-7e35-43ca-b1cb-23cf34912e33' User entered 'No (N)'	System	03 Sep 2020 21:51:13
	System	03 Sep 2020 21:51:13

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '73ffe50a-7e35-43ca-b1cb-23cf34912e33'	System	03 Sep 2020 21:51:13
User entered 'None (1)'	System	03 Sep 2020 21:51:13

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:12', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '73ffe50a-7e35-43ca-b1cb-23cf34912e33' User entered '03 Sep 2020 14:51'	System	03 Sep 2020 21:51:13
	System	03 Sep 2020 21:51:13

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 14:29'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 16:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:33:52', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2eb3eeab-9873-4520-a5f3-4e768d3e6780' User entered 'None (1)'	System	04 Sep 2020 13:34:43
	System	04 Sep 2020 13:34:43

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:33:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2eb3eeab-9873-4520-a5f3-4e768d3e6780' User entered 'No (N)'	System	04 Sep 2020 13:34:43
	System	04 Sep 2020 13:34:43

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2eb3eeab-9873-4520-a5f3-4e768d3e6780' User entered 'No (N)'	System	04 Sep 2020 13:34:43
	System	04 Sep 2020 13:34:43

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:27', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2eb3eeab-9873-4520-a5f3-4e768d3e6780' User entered 'None (1)'	System	04 Sep 2020 13:34:43
	System	04 Sep 2020 13:34:43

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2eb3eeab-9873-4520-a5f3-4e768d3e6780' User entered '04 Sep 2020 06:34'	System	04 Sep 2020 13:34:43
	System	04 Sep 2020 13:34:43

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 17:54'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 2'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:07:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a4508cb4-6d3a-40d5-9bdb-d4b95960a206'	System	05 Sep 2020 05:08:44
User entered 'None (1)'	System	05 Sep 2020 05:08:44

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a4508cb4-6d3a-40d5-9bdb-d4b95960a206' User entered 'No (N)'	System	05 Sep 2020 05:08:44
	System	05 Sep 2020 05:08:44

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:07', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a4508cb4-6d3a-40d5-9bdb-d4b95960a206' User entered 'No (N)'	System	05 Sep 2020 05:08:44
	System	05 Sep 2020 05:08:44

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a4508cb4-6d3a-40d5-9bdb-d4b95960a206' User entered 'None (1)'	System	05 Sep 2020 05:08:44
	System	05 Sep 2020 05:08:44

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a4508cb4-6d3a-40d5-9bdb-d4b95960a206' User entered '04 Sep 2020 22:08'	System	05 Sep 2020 05:08:44
	System	05 Sep 2020 05:08:44

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 3'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:16:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e7cb4892-ddfb-482b-b0ab-a260ee74949e' User entered 'None (1)'	System	06 Sep 2020 04:17:32
	System	06 Sep 2020 04:17:32

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:00', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e7cb4892-ddfb-482b-b0ab-a260ee74949e' User entered 'No (N)'	System	06 Sep 2020 04:17:32
	System	06 Sep 2020 04:17:32

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:04', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e7cb4892-ddfb-482b-b0ab-a260ee74949e' User entered 'No (N)'	System	06 Sep 2020 04:17:32
	System	06 Sep 2020 04:17:32

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e7cb4892-ddfb-482b-b0ab-a260ee74949e' User entered 'None (1)'	System	06 Sep 2020 04:17:32
	System	06 Sep 2020 04:17:32

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e7cb4892-ddfb-482b-b0ab-a260ee74949e' User entered '05 Sep 2020 21:17'	System	06 Sep 2020 04:17:32
	System	06 Sep 2020 04:17:32

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 4'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:47', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '557b532a-c83b-4568-9423-15ca9041d9f5' User entered 'None (1)'	System	07 Sep 2020 04:09:24
	System	07 Sep 2020 04:09:24

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '557b532a-c83b-4568-9423-15ca9041d9f5' User entered 'No (N)'	System	07 Sep 2020 04:09:24
	System	07 Sep 2020 04:09:24

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:08:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '557b532a-c83b-4568-9423-15ca9041d9f5' User entered 'No (N)'	System	07 Sep 2020 04:09:24
	System	07 Sep 2020 04:09:24

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '557b532a-c83b-4568-9423-15ca9041d9f5' User entered 'None (1)'	System	07 Sep 2020 04:09:24
	System	07 Sep 2020 04:09:24

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '557b532a-c83b-4568-9423-15ea9041d9f5' User entered '06 Sep 2020 21:09'	System	07 Sep 2020 04:09:24
	System	07 Sep 2020 04:09:24

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 5'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee11710b-5eb6-484b-ac38-7bb5563d85d3' User entered 'None (1)'	System	08 Sep 2020 04:19:25
	System	08 Sep 2020 04:19:25

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee11710b-5eb6-484b-ac38-7bb5563d85d3' User entered 'No (N)'	System	08 Sep 2020 04:19:25
	System	08 Sep 2020 04:19:25

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee11710b-5eb6-484b-ac38-7bb5563d85d3' User entered 'No (N)'	System	08 Sep 2020 04:19:25
	System	08 Sep 2020 04:19:25

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee11710b-5eb6-484b-ac38-7bb5563d85d3' User entered 'None (1)'	System	08 Sep 2020 04:19:25
	System	08 Sep 2020 04:19:25

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee11710b-5eb6-484b-ac38-7bb5563d85d3' User entered '07 Sep 2020 21:19'	System	08 Sep 2020 04:19:25
	System	08 Sep 2020 04:19:25

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 6'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5e5af655-1af7-4da8-954e-2f2f21932933' User entered 'None (1)'	System	09 Sep 2020 03:28:29
	System	09 Sep 2020 03:28:29

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5e5af655-1af7-4da8-954e-2f2f21932933' User entered 'No (N)'	System	09 Sep 2020 03:28:29
	System	09 Sep 2020 03:28:29

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:27:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5e5af655-1af7-4da8-954e-2f2f21932933' User entered 'No (N)'	System	09 Sep 2020 03:28:29
	System	09 Sep 2020 03:28:29

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5e5af655-1af7-4da8-954e-2f2f21932933' User entered 'None (1)'	System	09 Sep 2020 03:28:29
	System	09 Sep 2020 03:28:29

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:28', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5e5af655-1af7-4da8-954e-2f2f21932933' User entered '08 Sep 2020 20:28'	System	09 Sep 2020 03:28:29
	System	09 Sep 2020 03:28:29

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 7'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7c2dae0b-329c-4ccd-8f3b-0f0d121c0a0f' User entered 'None (1)'	System	10 Sep 2020 02:41:21
	System	10 Sep 2020 02:41:21

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7c2dae0b-329c-4ccd-8f3b-0f0d121c0a0f' User entered 'No (N)'	System	10 Sep 2020 02:41:21
	System	10 Sep 2020 02:41:21

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7c2dae0b-329c-4ccd-8f3b-0f0d121c0a0f' User entered 'No (N)'	System	10 Sep 2020 02:41:21
	System	10 Sep 2020 02:41:21

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:12', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7c2dae0b-329c-4ccd-8f3b-0f0d121c0a0f' User entered 'None (1)'	System	10 Sep 2020 02:41:21
	System	10 Sep 2020 02:41:21

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:19', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7c2dae0b-329c-4ccd-8f3b-0f0d121c0a0f' User entered '09 Sep 2020 19:41'	System	10 Sep 2020 02:41:21
	System	10 Sep 2020 02:41:21

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:22', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:28', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:32', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'None (0)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered 'No (N)'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-03T14:51:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '75734450-2e91-41b1-be2d-72a7ba1501cb' User entered '03 Sep 2020 14:51'	System	03 Sep 2020 21:52:00
	System	03 Sep 2020 21:52:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 14:29'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 16:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:53', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:34:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:35:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:35:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:35:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered 'None (0)'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:35:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05'	System	04 Sep 2020 13:35:28
User entered 'No (N)'	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T06:35:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b758a801-e429-4325-90b4-318129965a05' User entered '04 Sep 2020 06:35'	System	04 Sep 2020 13:35:28
	System	04 Sep 2020 13:35:28

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Sep 2020 17:54'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 2'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:52', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:08:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:09:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:09:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:09:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'None (0)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:09:16', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered 'No (N)'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-04T22:09:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7bb4bf73-e5fb-4c9e-b127-d85c70c68b65' User entered '04 Sep 2020 22:09'	System	05 Sep 2020 05:09:34
	System	05 Sep 2020 05:09:34

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 3'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:53', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:17:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:18:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'None (0)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:18:09', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered 'No (N)'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-05T21:18:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c6fb97a6-4a7a-4a5a-9714-61a1196ff8c5' User entered '05 Sep 2020 21:18'	System	06 Sep 2020 04:18:21
	System	06 Sep 2020 04:18:21

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 4'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:53', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:09:56', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'None (0)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:10:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered 'No (N)'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-06T21:10:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '59fc4f34-b1c4-4db0-b9e6-16a0bb867c59' User entered '06 Sep 2020 21:10'	System	07 Sep 2020 04:10:14
	System	07 Sep 2020 04:10:14

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 5'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:35', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'None (0)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered 'No (N)'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-07T21:19:54', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de669ad5-e0a7-46a0-99b3-4fba73def984' User entered '07 Sep 2020 21:19'	System	08 Sep 2020 04:20:00
	System	08 Sep 2020 04:20:00

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 6'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:35', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:41', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:47', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'None (0)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:28:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered 'No (N)'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-08T20:29:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8ba71d9c-4904-40f2-895b-d17e945f98e7' User entered '08 Sep 2020 20:29'	System	09 Sep 2020 03:29:09
	System	09 Sep 2020 03:29:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 7'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:41', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:46', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered 'None (0)'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:41:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798'	System	10 Sep 2020 02:42:09
User entered 'No (N)'	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-09-09T19:42:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b011dade-2755-4675-a2b8-4c0f58d20798' User entered '09 Sep 2020 19:42'	System	10 Sep 2020 02:42:09
	System	10 Sep 2020 02:42:09

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:26:50

US3582102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:01:53
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:11:00

US3582102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:01:53
User entered '10 Sep 2020'	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:11:00

US3582102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:01:53
User entered 'Contact Made (CONTACT MADE)'	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:11:00

US3582102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:01:53
User entered empty.	Barbara Carste (b) (4) (b) (4)	11 Sep 2020 22:11:00

US3582102

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:02:49
User entered 'Yes (Y)'	V1 Iran (b) (4)	18 Sep 2020 18:43:23

US3582102

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'l'	System	18 Sep 2020 18:43:23

US3582102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:02:54
User entered 'Yes (Y)'	V1 Iran (b) (4)	18 Sep 2020 18:43:34

US3582102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:02:54
User entered '17 Sep 2020'	V1 Iran (b) (4)	18 Sep 2020 18:43:34

US3582102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:02:54
User entered 'Contact Made (CONTACT MADE)'	V1 Tran (b) (4)	18 Sep 2020 18:43:34

US3582102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:02:54
User entered empty.	Vi Tran (b) (4)	18 Sep 2020 18:43:34

US3582102

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:07
User entered 'Yes (Y)'	V1 Iran (b) (4)	18 Sep 2020 18:43:39

US3582102

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'I'	System	18 Sep 2020 18:43:39

US3582102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:20
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	25 Sep 2020 22:53:33

US3582102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:20
User entered '24 Sep 2020'	Roxanne Erolin (b) (4) (b) (4)	25 Sep 2020 22:53:33

US3582102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:20
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	25 Sep 2020 22:53:33

US3582102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:20
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	25 Sep 2020 22:53:33

US3582102

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:32
User entered 'Yes (Y)'	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:32

US3582102

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'l'	System	01 Oct 2020 18:36:32

US3582102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:41
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:54:55

US3582102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:41
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:54:55

US3582102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:41
User entered 'Clinic (Clinic)'	Stella Lee (b) (4)	02 Oct 2020 19:54:55

US3582102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'VISIT2'	System	02 Oct 2020 19:54:55

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '11:00'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '01 Oct 2020 11:00'	System	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '99' F	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered 'Other (Other)'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered 'Temporal'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '75'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'bpm'	System	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '16'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'breaths/min'	System	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '134'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '60'	Stella Lee (b) (4)	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Oct 2020 19:55:20

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '12:04'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '01 Oct 2020 12:04'	System	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '98.3' F	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered 'Oral (Oral)'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered empty.	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '66'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'bpm'	System	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '20'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'breaths/min'	System	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '147'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
Query 'Please verify, per source 66 is documented and 60 is crossed off.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 19:07:21
User opened query 'Please verify, per source 66 is documented and 60 is crossed off.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 19:05:12
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:03:48
User entered '60'	Stella Lee (b) (4)	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Oct 2020 19:56:10

US3582102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:44
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:56:21

US3582102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:44
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:56:21

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered 'Yes (Y)'	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered empty.	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

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)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered empty.	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered '1 Oct 2020'	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered '11:33'	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '1 Oct 2020 11:33'	System	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered 'Left Arm (LEFT ARM)'	Melissa Scheer (b) (4) (b) (4)	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:07:57
User entered 'ONCE'	System	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 18:36:52

US3582102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:03
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:56:33

US3582102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:03
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:56:33

US3582102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:03
User entered '11:18'	Stella Lee (b) (4)	02 Oct 2020 19:56:33

US3582102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '01 Oct 2020 11:18'	System	02 Oct 2020 19:56:33

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:16
User entered '01 Oct 2020'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:16
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:16
User entered '11:26'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '01 Oct 2020 11:26'	System	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:16
User entered 'No (N)'	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:08:16
User entered empty.	Stella Lee (b) (4)	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered empty.	System	02 Oct 2020 19:56:42

US3582102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:45:25
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Oct 2020 18:17:39

US3582102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'I'	System	09 Oct 2020 18:17:39

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:12:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '148bde1c-2f14-465b-b405-853fd5c821fa' User entered 'Yes (Y)'	System	01 Oct 2020 19:12:54
	System	01 Oct 2020 19:12:54

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:12:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '148bde1c-2f14-465b-b405-853fd5c821fa' User entered '98.3'	System	01 Oct 2020 19:12:54
	System	01 Oct 2020 19:12:54

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:12:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '148bde1c-2f14-465b-b405-853fd5c821fa' User entered 'No (N)'	System	01 Oct 2020 19:12:54
	System	01 Oct 2020 19:12:54

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:12:52', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '148bde1c-2f14-465b-b405-853fd5c821fa' User entered '01 Oct 2020 12:12'	System	01 Oct 2020 19:12:54
	System	01 Oct 2020 19:12:54

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 11:53'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 14:23'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:11:12', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '09f87004-99ab-4a29-847d-05d04ac40bdf' User entered 'Yes (Y)'	System	02 Oct 2020 12:12:05
	System	02 Oct 2020 12:12:05

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:11:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '09f87004-99ab-4a29-847d-05d04ac40bdf' User entered '97.3'	System	02 Oct 2020 12:12:05
	System	02 Oct 2020 12:12:05

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:11:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '09f87004-99ab-4a29-847d-05d04ac40bdf' User entered 'No (N)'	System	02 Oct 2020 12:12:05
	System	02 Oct 2020 12:12:05

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:12:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '09f87004-99ab-4a29-847d-05d04ac40bdf' User entered '02 Oct 2020 05:12'	System	02 Oct 2020 12:12:05
	System	02 Oct 2020 12:12:05

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 15:18'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 2'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 3'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:15:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2c955a1a-a39a-4f35-acde-5794e617cbe6' User entered 'Yes (Y)'	System	04 Oct 2020 03:16:04
	System	04 Oct 2020 03:16:04

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:15:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2c955a1a-a39a-4f35-acde-5794e617cbe6' User entered '98.4'	System	04 Oct 2020 03:16:04
	System	04 Oct 2020 03:16:04

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:15:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2c955a1a-a39a-4f35-acde-5794e617cbe6' User entered 'No (N)'	System	04 Oct 2020 03:16:04
	System	04 Oct 2020 03:16:04

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:16:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2c955a1a-a39a-4f35-acde-5794e617cbe6' User entered '03 Oct 2020 20:16'	System	04 Oct 2020 03:16:04
	System	04 Oct 2020 03:16:04

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 4'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:30:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee4a221c-a680-443b-8d36-d81fa5963c2d' User entered 'Yes (Y)'	System	05 Oct 2020 05:30:47
	System	05 Oct 2020 05:30:47

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:30:32', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee4a221c-a680-443b-8d36-d81fa5963c2d' User entered '98.0'	System	05 Oct 2020 05:30:47
	System	05 Oct 2020 05:30:47

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:30:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee4a221c-a680-443b-8d36-d81fa5963c2d' User entered 'No (N)'	System	05 Oct 2020 05:30:47
	System	05 Oct 2020 05:30:47

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:30:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ee4a221c-a680-443b-8d36-d81fa5963c2d' User entered '04 Oct 2020 22:30'	System	05 Oct 2020 05:30:47
	System	05 Oct 2020 05:30:47

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 5'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:09:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '9a088853-446a-416b-ac7d-ced2a5f2c31f' User entered 'Yes (Y)'	System	06 Oct 2020 02:10:22
	System	06 Oct 2020 02:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '9a088853-446a-416b-ac7d-ced2a5f2c31f' User entered '98.2'	System	06 Oct 2020 02:10:22
	System	06 Oct 2020 02:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '9a088853-446a-416b-ac7d-ced2a5f2c31f' User entered 'No (N)'	System	06 Oct 2020 02:10:22
	System	06 Oct 2020 02:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:20', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '9a088853-446a-416b-ac7d-ced2a5f2c31f' User entered '05 Oct 2020 19:10'	System	06 Oct 2020 02:10:22
	System	06 Oct 2020 02:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 6'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:15:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '738649f2-107f-462d-9293-2e8608e259c9' User entered 'Yes (Y)'	System	07 Oct 2020 03:16:06
	System	07 Oct 2020 03:16:06

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:15:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '738649f2-107f-462d-9293-2e8608e259c9' User entered '98.6'	System	07 Oct 2020 03:16:06
	System	07 Oct 2020 03:16:06

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:15:56', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '738649f2-107f-462d-9293-2e8608e259c9' User entered 'No (N)'	System	07 Oct 2020 03:16:06
	System	07 Oct 2020 03:16:06

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:04', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '738649f2-107f-462d-9293-2e8608e259c9' User entered '06 Oct 2020 20:16'	System	07 Oct 2020 03:16:06
	System	07 Oct 2020 03:16:06

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 7'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1c9521e4-d443-4abf-a097-f69cfe064ba4' User entered 'Yes (Y)'	System	08 Oct 2020 01:42:26
	System	08 Oct 2020 01:42:26

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1c9521e4-d443-4abf-a097-f69cfe064ba4' User entered '97.6'	System	08 Oct 2020 01:42:26
	System	08 Oct 2020 01:42:26

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1c9521e4-d443-4abf-a097-f69efe064ba4' User entered 'No (N)'	System	08 Oct 2020 01:42:26
	System	08 Oct 2020 01:42:26

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1c9521e4-d443-4abf-a097-f69efe064ba4' User entered '07 Oct 2020 18:42'	System	08 Oct 2020 01:42:26
	System	08 Oct 2020 01:42:26

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:13:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de2e92d6-d345-487f-85ad-ffb08f43f97b' User entered 'None (1)'	System	01 Oct 2020 19:14:58
	System	01 Oct 2020 19:14:58

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:14:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de2e92d6-d345-487f-85ad-ffb08f43f97b' User entered 'No (N)'	System	01 Oct 2020 19:14:58
	System	01 Oct 2020 19:14:58

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:14:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de2e92d6-d345-487f-85ad-ffb08f43f97b' User entered 'No (N)'	System	01 Oct 2020 19:14:58
	System	01 Oct 2020 19:14:58

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:14:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de2e92d6-d345-487f-85ad-ffb08f43f97b' User entered 'None (1)'	System	01 Oct 2020 19:14:58
	System	01 Oct 2020 19:14:58

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:14:56', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'de2e92d6-d345-487f-85ad-ffb08f43f97b' User entered '01 Oct 2020 12:14'	System	01 Oct 2020 19:14:58
	System	01 Oct 2020 19:14:58

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 11:53'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 14:23'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:08:56', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '65f4002a-d1d5-4efa-b370-f6d3236f2a00'	System	02 Oct 2020 12:09:40
User entered 'None (1)'	System	02 Oct 2020 12:09:40

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '65f4002a-d1d5-4efa-b370-f6d3236f2a00' User entered 'No (N)'	System	02 Oct 2020 12:09:40
	System	02 Oct 2020 12:09:40

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '65f4002a-d1d5-4efa-b370-f6d3236f2a00' User entered 'No (N)'	System	02 Oct 2020 12:09:40
	System	02 Oct 2020 12:09:40

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '65f4002a-d1d5-4efa-b370-f6d3236f2a00'	System	02 Oct 2020 12:09:40
User entered 'None (1)'	System	02 Oct 2020 12:09:40

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '65f4002a-d1d5-4efa-b370-f6d3236f2a00' User entered '02 Oct 2020 05:09'	System	02 Oct 2020 12:09:40
	System	02 Oct 2020 12:09:40

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 15:18'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 2'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 3'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:16:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd80992be-cb6c-44f5-9063-68c040e0d9d5' User entered 'None (1)'	System	04 Oct 2020 03:17:20
	System	04 Oct 2020 03:17:20

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:16:45', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd80992be-cb6c-44f5-9063-68c040e0d9d5' User entered 'No (N)'	System	04 Oct 2020 03:17:20
	System	04 Oct 2020 03:17:20

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:16:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd80992be-cb6c-44f5-9063-68c040e0d9d5' User entered 'No (N)'	System	04 Oct 2020 03:17:20
	System	04 Oct 2020 03:17:20

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd80992be-cb6c-44f5-9063-68c040e0d9d5' User entered 'None (1)'	System	04 Oct 2020 03:17:20
	System	04 Oct 2020 03:17:20

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'd80992be-cb6c-44f5-9063-68c040e0d9d5' User entered '03 Oct 2020 20:17'	System	04 Oct 2020 03:17:20
	System	04 Oct 2020 03:17:20

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 4'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:30:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'cbf67750-8131-4343-964a-577d0b297dd3'	System	05 Oct 2020 05:32:08
User entered 'None (1)'	System	05 Oct 2020 05:32:08

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:31:07', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'cbf67750-8131-4343-964a-577d0b297dd3' User entered 'No (N)'	System	05 Oct 2020 05:32:08
	System	05 Oct 2020 05:32:08

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:31:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'cbf67750-8131-4343-964a-577d0b297dd3' User entered 'No (N)'	System	05 Oct 2020 05:32:08
	System	05 Oct 2020 05:32:08

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:31:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'cbf67750-8131-4343-964a-577d0b297dd3' User entered 'None (1)'	System	05 Oct 2020 05:32:08
	System	05 Oct 2020 05:32:08

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'cbf67750-8131-4343-964a-577d0b297dd3' User entered '04 Oct 2020 22:32'	System	05 Oct 2020 05:32:08
	System	05 Oct 2020 05:32:08

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 5'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:29', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'f0b25cec-69ea-45d0-bb6a-03cfc8e84969'	System	06 Oct 2020 02:10:51
User entered 'None (1)'	System	06 Oct 2020 02:10:51

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'f0b25cec-69ea-45d0-bb6a-03cfc8e84969' User entered 'No (N)'	System	06 Oct 2020 02:10:51
	System	06 Oct 2020 02:10:51

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'f0b25cec-69ea-45d0-bb6a-03cfc8e84969' User entered 'No (N)'	System	06 Oct 2020 02:10:51
	System	06 Oct 2020 02:10:51

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'f0b25cec-69ea-45d0-bb6a-03cfc8e84969' User entered 'None (1)'	System	06 Oct 2020 02:10:51
	System	06 Oct 2020 02:10:51

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'f0b25cec-69ea-45d0-bb6a-03cfc8e84969' User entered '05 Oct 2020 19:10'	System	06 Oct 2020 02:10:51
	System	06 Oct 2020 02:10:51

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 6'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:08', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6f0b6d2f-e60a-465d-94c2-0f7f03b81b51' User entered 'None (1)'	System	07 Oct 2020 03:16:50
	System	07 Oct 2020 03:16:50

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6f0b6d2f-e60a-465d-94c2-0f7f03b81b51' User entered 'No (N)'	System	07 Oct 2020 03:16:50
	System	07 Oct 2020 03:16:50

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6f0b6d2f-e60a-465d-94c2-0f7f03b81b51' User entered 'No (N)'	System	07 Oct 2020 03:16:50
	System	07 Oct 2020 03:16:50

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6f0b6d2f-e60a-465d-94c2-0f7f03b81b51' User entered 'None (1)'	System	07 Oct 2020 03:16:50
	System	07 Oct 2020 03:16:50

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6f0b6d2f-e60a-465d-94c2-0f7f03b81b51' User entered '06 Oct 2020 20:16'	System	07 Oct 2020 03:16:50
	System	07 Oct 2020 03:16:50

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 7'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '419d431e-9203-4b90-bff1-2a5eafe15dc2'	System	08 Oct 2020 01:42:56
User entered 'None (1)'	System	08 Oct 2020 01:42:56

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '419d431e-9203-4b90-bff1-2a5eafe15dc2'	System	08 Oct 2020 01:42:56
User entered 'No (N)'	System	08 Oct 2020 01:42:56

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '419d431e-9203-4b90-bff1-2a5eafe15dc2'	System	08 Oct 2020 01:42:56
User entered 'No (N)'	System	08 Oct 2020 01:42:56

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '419d431e-9203-4b90-bff1-2a5eafe15dc2'	System	08 Oct 2020 01:42:56
User entered 'None (1)'	System	08 Oct 2020 01:42:56

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:54', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '419d431e-9203-4b90-bff1-2a5eafe15dc2'	System	08 Oct 2020 01:42:56
User entered '07 Oct 2020 18:42'	System	08 Oct 2020 01:42:56

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:07', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:21', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'None (0)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366' User entered 'No (N)'	System	01 Oct 2020 19:15:48
	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-01T12:15:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ba0403c3-bfaa-423f-8d78-0d6949cb8366'	System	01 Oct 2020 19:15:48
User entered '01 Oct 2020 12:15'	System	01 Oct 2020 19:15:48

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 11:53'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 14:23'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:43', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:46', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:53', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:09:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'None (0)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:12:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered 'No (N)'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-02T05:12:21', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '5b0cf424-25ea-421a-8262-1ec32631346a' User entered '02 Oct 2020 05:12'	System	02 Oct 2020 12:12:25
	System	02 Oct 2020 12:12:25

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '01 Oct 2020 15:18'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 2'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 3'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:27', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:29', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'None (0)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered 'No (N)'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-03T20:17:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0de4726f-e18a-4212-9e26-65c64f0161be' User entered '03 Oct 2020 20:17'	System	04 Oct 2020 03:17:58
	System	04 Oct 2020 03:17:58

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 4'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:12', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:20', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:28', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'None (0)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered 'No (N)'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-04T22:32:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '0629d4dd-c4c0-4128-a4c8-11c1768648d0' User entered '04 Oct 2020 22:32'	System	05 Oct 2020 05:32:45
	System	05 Oct 2020 05:32:45

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 5'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:10:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:00', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:02', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:07', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'None (0)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered 'No (N)'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-05T19:11:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '362ed3fe-9d4e-4e04-b541-d9138d62bb1e' User entered '05 Oct 2020 19:11'	System	06 Oct 2020 02:11:27
	System	06 Oct 2020 02:11:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 6'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:54', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:16:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:00', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:09', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:12', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'None (0)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered 'No (N)'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-06T20:17:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'be536b41-ffbf-49a7-a31f-8c229e359601' User entered '06 Oct 2020 20:17'	System	07 Oct 2020 03:17:27
	System	07 Oct 2020 03:17:27

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	01 Oct 2020 18:36:52
User entered 'Day 7'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:42:59', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:07', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'None (0)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered 'No (N)'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-10-07T18:43:22', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4ccf0fd1-2bd1-4031-a12d-1ed827731a56' User entered '07 Oct 2020 18:43'	System	08 Oct 2020 01:43:24
	System	08 Oct 2020 01:43:24

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 18:36:52

US3582102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 18:36:52

US3582102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:45:37
User entered 'Yes (Y)'	Stella Lee (b) (4)	09 Oct 2020 18:17:49

US3582102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:45:37
User entered '08 Oct 2020'	Stella Lee (b) (4)	09 Oct 2020 18:17:49

US3582102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:45:37
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	09 Oct 2020 18:17:49

US3582102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:45:37
User entered empty.	Stella Lee (b) (4)	09 Oct 2020 18:17:49

US3582102

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:23
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:00:11

US3582102

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'I'	System	16 Oct 2020 01:00:11

US3582102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:44
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:00:32

US3582102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:44
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 01:01:28
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Oct 2020 01:01:28
User entered '15 Oct 2020' reason for change: Data Entry Error	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:01:28
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 01:00:32
User entered '14 Oct 2020'	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:00:32

US3582102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:44
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:00:32

US3582102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:44
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	16 Oct 2020 01:00:32

US3582102

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:46:56
User entered 'Yes (Y)'	Stella Lee (b) (4)	23 Oct 2020 20:02:22

US3582102

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'l'	System	23 Oct 2020 20:02:22

US3582102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:20
User entered 'Yes (Y)'	Stella Lee (b) (4)	23 Oct 2020 20:02:34

US3582102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:20
User entered '22 Oct 2020'	Stella Lee (b) (4)	23 Oct 2020 20:02:34

US3582102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:20
User entered 'Contact Made (CONTACT MADE)'	Stella Lee (b) (4)	23 Oct 2020 20:02:34

US3582102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:20
User entered empty.	Stella Lee (b) (4)	23 Oct 2020 20:02:34

US3582102

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:31
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Nov 2020 21:17:33

US3582102

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'l'	System	02 Nov 2020 21:17:33

US3582102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:54
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Nov 2020 21:17:42

US3582102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:54
User entered '30 Oct 2020'	Stella Lee (b) (4)	02 Nov 2020 21:17:42

US3582102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:47:54
User entered 'Clinic (Clinic)'	Stella Lee (b) (4)	02 Nov 2020 21:17:42

US3582102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'VISIT3'	System	02 Nov 2020 21:17:42

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '30 Oct 2020'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '13:34'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '30 Oct 2020 13:34'	System	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '97.8' F	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered 'Other (Other)'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered 'Temporal'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '52'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'bpm'	System	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '16'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'breaths/min'	System	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '122'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:36
User entered '60'	Stella Lee (b) (4)	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'mmHg'	System	02 Nov 2020 21:18:05

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12

US3582102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12

US3582102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:43
User entered 'No (N)'	Stella Lee (b) (4)	02 Nov 2020 21:18:09

US3582102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:43
User entered empty.	Stella Lee (b) (4)	02 Nov 2020 21:18:09

US3582102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:49
User entered 'Yes (Y)'	Stella Lee (b) (4)	02 Nov 2020 21:18:19

US3582102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:49
User entered '30 Oct 2020'	Stella Lee (b) (4)	02 Nov 2020 21:18:19

US3582102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:48:49
User entered '13:48'	Stella Lee (b) (4)	02 Nov 2020 21:18:19

US3582102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered '30 Oct 2020 13:48'	System	02 Nov 2020 21:18:19

US3582102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:24:26
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:57:17

US3582102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'I'	System	25 Nov 2020 19:57:17

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 64'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-04T21:38:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a979448b-daf0-4b58-8a3b-e0bff8263a0a' User entered 'No (N)'	System	05 Nov 2020 05:38:33
	System	05 Nov 2020 05:38:33

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-04T21:38:23', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a979448b-daf0-4b58-8a3b-e0bff8263a0a' User entered 'No (N)'	System	05 Nov 2020 05:38:33
	System	05 Nov 2020 05:38:33

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-04T21:38:31', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a979448b-daf0-4b58-8a3b-e0bff8263a0a' User entered '04 Nov 2020 21:38:31'	System	05 Nov 2020 05:38:33
	System	05 Nov 2020 05:38:33

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 71'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-11T23:15:19', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '61b4006f-de12-408f-bcbf-53fd6ad3e898'	System	12 Nov 2020 07:15:38
User entered 'No (N)'	System	12 Nov 2020 07:15:38

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-11T23:15:27', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '61b4006f-de12-408f-bcbf-53fd6ad3e898'	System	12 Nov 2020 07:15:38
User entered 'No (N)'	System	12 Nov 2020 07:15:38

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-11T23:15:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '61b4006f-de12-408f-bcbf-53fd6ad3e898' User entered '11 Nov 2020 23:15:33'	System	12 Nov 2020 07:15:38
	System	12 Nov 2020 07:15:38

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered 'Day 78'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-17T13:53:56', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1e734bc0-f4d4-4121-ad2a-ff63a3055f17' User entered 'No (N)'	System	17 Nov 2020 21:54:23
	System	17 Nov 2020 21:54:23

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-17T13:54:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1e734bc0-f4d4-4121-ad2a-ff63a3055f17'	System	17 Nov 2020 21:54:23
User entered 'No (N)'	System	17 Nov 2020 21:54:23

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-17T13:54:21', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '1e734bc0-f4d4-4121-ad2a-ff63a3055f17' User entered '17 Nov 2020 13:54:21'	System	17 Nov 2020 21:54:23
	System	17 Nov 2020 21:54:23

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 21:26:50

US3582102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:10:22
Data entry locked.	System	03 Sep 2020 21:26:50
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 21:26:50

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-22T15:40:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ed4d679e-d776-485c-a69a-70068819f08b' User entered 'No (N)'	System	22 Nov 2020 23:40:55
	System	22 Nov 2020 23:40:55

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-22T15:40:44', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ed4d679e-d776-485c-a69a-70068819f08b' User entered 'No (N)'	System	22 Nov 2020 23:40:55
	System	22 Nov 2020 23:40:55

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-22T15:40:53', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ed4d679e-d776-485c-a69a-70068819f08b' User entered '22 Nov 2020 15:40:53'	System	22 Nov 2020 23:40:55
	System	22 Nov 2020 23:40:55

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-28T17:12:35', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8150b15d-3211-4158-b86f-a8a661733c12' User entered 'No (N)'	System	29 Nov 2020 01:12:50

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-28T17:12:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8150b15d-3211-4158-b86f-a8a661733c12'	System	29 Nov 2020 01:12:50
User entered 'No (N)'	System	29 Nov 2020 01:12:50

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-11-28T17:12:48', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '8150b15d-3211-4158-b86f-a8a661733c12'	System	29 Nov 2020 01:12:50
User entered '28 Nov 2020 17:12:48'	System	29 Nov 2020 01:12:50

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-05T14:47:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'aac58c8b-c004-42e6-8139-74d0c5f13e37' User entered 'No (N)'	System	05 Dec 2020 22:47:35
	System	05 Dec 2020 22:47:35

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-05T14:47:26', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'aac58c8b-c004-42e6-8139-74d0c5f13e37' User entered 'No (N)'	System	05 Dec 2020 22:47:35
	System	05 Dec 2020 22:47:35

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-05T14:47:32', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'aac58c8b-c004-42e6-8139-74d0c5f13e37' User entered '05 Dec 2020 14:47:32'	System	05 Dec 2020 22:47:35
	System	05 Dec 2020 22:47:35

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-13T11:26:55', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a2f6a847-c470-4013-bbdd-55c02876a9e3' User entered 'No (N)'	System	13 Dec 2020 19:27:13
	System	13 Dec 2020 19:27:13

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-13T11:27:00', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a2f6a847-c470-4013-bbdd-55c02876a9e3' User entered 'No (N)'	System	13 Dec 2020 19:27:13

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-13T11:27:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a2f6a847-c470-4013-bbdd-55c02876a9e3' User entered '13 Dec 2020 11:27:11'	System	13 Dec 2020 19:27:13
	System	13 Dec 2020 19:27:13

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-19T16:19:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3e87f9d5-605e-44aa-b39d-3b5b84f67329' User entered 'No (N)'	System	20 Dec 2020 00:20:14
	System	20 Dec 2020 00:20:14

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-19T16:19:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3e87f9d5-605e-44aa-b39d-3b5b84f67329' User entered 'No (N)'	System	20 Dec 2020 00:20:14

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-19T16:20:11', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3e87f9d5-605e-44aa-b39d-3b5b84f67329' User entered '19 Dec 2020 16:20:11'	System	20 Dec 2020 00:20:14
	System	20 Dec 2020 00:20:14

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-26T14:25:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4828902b-036d-4a9c-b4dc-f000d07cba1b' User entered 'No (N)'	System	26 Dec 2020 22:26:22
	System	26 Dec 2020 22:26:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-26T14:26:01', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4828902b-036d-4a9c-b4dc-f000d07cba1b' User entered 'No (N)'	System	26 Dec 2020 22:26:22
	System	26 Dec 2020 22:26:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2020-12-26T14:26:19', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4828902b-036d-4a9c-b4dc-f000d07cba1b' User entered '26 Dec 2020 14:26:19'	System	26 Dec 2020 22:26:22
	System	26 Dec 2020 22:26:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:21:45', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d' User entered 'Yes (Y)'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:22:18', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d' User entered 'No (N)'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:22:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d' User entered 'No (N)'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:22:40', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d' User entered 'Yes (Y)'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Please 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:23:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d'	System	03 Jan 2021 03:23:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-02T19:23:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '6e5cb55f-a3d0-4d48-bb07-2d625964942d' User entered '02 Jan 2021 19:23:49'	System	03 Jan 2021 03:23:57

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-10T20:24:22', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '914f742b-26e8-4d4e-9a69-7644326808ad' User entered 'No (N)'	System	11 Jan 2021 04:24:33

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-10T20:24:25', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '914f742b-26e8-4d4e-9a69-7644326808ad' User entered 'No (N)'	System	11 Jan 2021 04:24:33

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-10T20:24:31', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '914f742b-26e8-4d4e-9a69-7644326808ad' User entered '10 Jan 2021 20:24:31'	System	11 Jan 2021 04:24:33
	System	11 Jan 2021 04:24:33

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-16T13:15:27', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7f864e81-040e-4fd9-8246-3c04a85687e9' User entered 'No (N)'	System	16 Jan 2021 21:15:40
	System	16 Jan 2021 21:15:40

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-16T13:15:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7f864e81-040e-4fd9-8246-3c04a85687e9' User entered 'No (N)'	System	16 Jan 2021 21:15:40
	System	16 Jan 2021 21:15:40

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-16T13:15:37', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '7f864e81-040e-4fd9-8246-3c04a85687e9' User entered '16 Jan 2021 13:15:37'	System	16 Jan 2021 21:15:40
	System	16 Jan 2021 21:15:40

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-23T21:57:36', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4e37b50a-7e46-4d7d-9163-6bd86cd03aaa' User entered 'No (N)'	System	24 Jan 2021 05:57:59
	System	24 Jan 2021 05:57:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-23T21:57:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4e37b50a-7e46-4d7d-9163-6bd86cd03aaa' User entered 'No (N)'	System	24 Jan 2021 05:57:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-01-23T21:57:57', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '4e37b50a-7e46-4d7d-9163-6bd86cd03aaa' User entered '23 Jan 2021 21:57:57'	System	24 Jan 2021 05:57:59

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-03T15:00:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '88e60ca6-d09c-4b74-abe8-4be36c5a59c9' User entered 'No (N)'	System	03 Feb 2021 23:02:17
	System	03 Feb 2021 23:02:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-03T15:00:52', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '88e60ca6-d09c-4b74-abe8-4be36c5a59c9' User entered 'No (N)'	System	03 Feb 2021 23:02:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-03T15:00:58', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '88e60ca6-d09c-4b74-abe8-4be36c5a59c9' User entered '03 Feb 2021 15:00:58'	System	03 Feb 2021 23:02:17
	System	03 Feb 2021 23:02:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-07T19:17:30', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b675fb34-1d36-42f2-89bb-852790524c7b' User entered 'No (N)'	System	08 Feb 2021 03:17:53
	System	08 Feb 2021 03:17:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-07T19:17:39', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b675fb34-1d36-42f2-89bb-852790524c7b' User entered 'No (N)'	System	08 Feb 2021 03:17:53
	System	08 Feb 2021 03:17:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-07T19:17:49', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'b675fb34-1d36-42f2-89bb-852790524c7b' User entered '07 Feb 2021 19:17:49'	System	08 Feb 2021 03:17:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-20T14:15:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ca314af5-89a7-426f-ae8-2c2cc729ddf2' User entered 'No (N)'	System	20 Feb 2021 22:15:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-20T14:15:09', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ca314af5-89a7-426f-aee8-2c2cc729ddf2' User entered 'No (N)'	System	20 Feb 2021 22:15:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-20T14:15:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'ca314af5-89a7-426f-ae8-2c2cc729ddf2' User entered '20 Feb 2021 14:15:15'	System	20 Feb 2021 22:15:17
	System	20 Feb 2021 22:15:17

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:21:10', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659' User entered 'Yes (Y)'	System	28 Feb 2021 07:23:01
	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:21:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659' User entered 'No (N)'	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:21:32', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659' User entered 'No (N)'	System	28 Feb 2021 07:23:01
	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:21:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659' User entered 'Yes (Y)'	System	28 Feb 2021 07:23:01
	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Please 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:22:13', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659'	System	28 Feb 2021 07:23:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-02-27T23:22:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '563ef4cf-89d2-4d9c-b230-18bf48b46659' User entered '27 Feb 2021 23:22:50'	System	28 Feb 2021 07:23:01
	System	28 Feb 2021 07:23:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-08T09:49:59', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e93dd63a-8d86-4cb5-a992-4791540dc3d2'	System	08 Mar 2021 17:50:22
User entered 'No (N)'	System	08 Mar 2021 17:50:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-08T09:50:03', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e93dd63a-8d86-4cb5-a992-4791540dc3d2'	System	08 Mar 2021 17:50:22
User entered 'No (N)'	System	08 Mar 2021 17:50:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-08T09:50:17', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'e93dd63a-8d86-4cb5-a992-4791540dc3d2'	System	08 Mar 2021 17:50:22
User entered '08 Mar 2021 09:50:17'	System	08 Mar 2021 17:50:22

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-14T19:08:42', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c68bcc36-69d7-4d68-beec-192839f54b25' User entered 'No (N)'	System	15 Mar 2021 02:09:01
	System	15 Mar 2021 02:09:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-14T19:08:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c68bcc36-69d7-4d68-beec-192839f54b25' User entered 'No (N)'	System	15 Mar 2021 02:09:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-14T19:08:59', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'c68bcc36-69d7-4d68-beec-192839f54b25' User entered '14 Mar 2021 19:08:59'	System	15 Mar 2021 02:09:01
	System	15 Mar 2021 02:09:01

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-24T18:50:41', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a56531b5-2268-46c9-a010-963216c7ddc3' User entered 'No (N)'	System	25 Mar 2021 01:50:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-24T18:50:45', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a56531b5-2268-46c9-a010-963216c7ddc3'	System	25 Mar 2021 01:50:53
User entered 'No (N)'	System	25 Mar 2021 01:50:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-24T18:50:50', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'a56531b5-2268-46c9-a010-963216c7ddc3'	System	25 Mar 2021 01:50:53
User entered '24 Mar 2021 18:50:50'	System	25 Mar 2021 01:50:53

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-28T06:05:22', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2a2f2d60-3200-4284-aba2-5e4054cf9a8e' User entered 'No (N)'	System	28 Mar 2021 13:05:41
	System	28 Mar 2021 13:05:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-28T06:05:29', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2a2f2d60-3200-4284-aba2-5e4054cf9a8e' User entered 'No (N)'	System	28 Mar 2021 13:05:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-28T06:05:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2a2f2d60-3200-4284-aba2-5e4054cf9a8e' User entered '28 Mar 2021 06:05:38'	System	28 Mar 2021 13:05:41
	System	28 Mar 2021 13:05:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-03T09:36:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'dc726b15-5dd4-47b9-9565-c9bdd7822409' User entered 'No (N)'	System	03 Apr 2021 16:36:18

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-03T09:36:09', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'dc726b15-5dd4-47b9-9565-c9bdd7822409' User entered 'No (N)'	System	03 Apr 2021 16:36:18

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-03T09:36:14', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: 'dc726b15-5dd4-47b9-9565-c9bdd7822409'	System	03 Apr 2021 16:36:18
User entered '03 Apr 2021 09:36:14'	System	03 Apr 2021 16:36:18

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-17T20:33:28', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '96821a40-fbd8-4c86-a09f-81213519ff9c' User entered 'No (N)'	System	18 Apr 2021 03:33:41
	System	18 Apr 2021 03:33:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-17T20:33:32', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '96821a40-fbd8-4c86-a09f-81213519ff9c' User entered 'No (N)'	System	18 Apr 2021 03:33:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-17T20:33:38', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '96821a40-fbd8-4c86-a09f-81213519ff9c' User entered '17 Apr 2021 20:33:38'	System	18 Apr 2021 03:33:41
	System	18 Apr 2021 03:33:41

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-25T13:45:24', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '04a00c62-4c2a-4325-b6f6-2b9230f05e53' User entered 'No (N)'	System	25 Apr 2021 20:46:25
	System	25 Apr 2021 20:46:25

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-25T13:45:35', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '04a00c62-4c2a-4325-b6f6-2b9230f05e53' User entered 'Yes (Y)'	System	25 Apr 2021 20:46:25
	System	25 Apr 2021 20:46:25

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Please 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-25T13:46:06', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '04a00c62-4c2a-4325-b6f6-2b9230f05e53'	System	25 Apr 2021 20:46:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 20:46:25

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-04-25T13:46:15', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '04a00c62-4c2a-4325-b6f6-2b9230f05e53' User entered '25 Apr 2021 13:46:15'	System	25 Apr 2021 20:46:25
	System	25 Apr 2021 20:46:25

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-05-01T18:09:05', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3728c271-2b36-4f2b-b620-9bea582c9497'	System	02 May 2021 01:13:10
User entered 'No (N)'	System	02 May 2021 01:13:10

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Have you been exposed to someone with 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 (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-05-01T18:09:22', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3728c271-2b36-4f2b-b620-9bea582c9497'	System	02 May 2021 01:13:10
User entered 'No (N)'	System	02 May 2021 01:13:10

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-05-01T18:09:26', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '3728c271-2b36-4f2b-b620-9bea582c9497'	System	02 May 2021 01:13:10
User entered '01 May 2021 18:09:26'	System	02 May 2021 01:13:10

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:32:11

US3582102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:11
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:32:11

US3582102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:00:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-08T09:50:33', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2f6d217d-636d-4ce7-ba08-a7d045f94ed2'	System	08 Mar 2021 17:50:53
User entered 'No (N)'	System	08 Mar 2021 17:50:53

US3582102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:00:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3902F646-EFDB-49B5-845F-07DF1DF8A289)', Time: '2021-03-08T09:50:51', User OID: 'PatientReportedOutcome (US3582102)', ODM File OID: '2f6d217d-636d-4ce7-ba08-a7d045f94ed2' User entered '08 Mar 2021 09:50:51'	System	08 Mar 2021 17:50:53
	System	08 Mar 2021 17:50:53

US3582102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:24:14
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:57:44

US3582102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:24:14
User entered '23 Nov 2020'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:57:44

US3582102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:24:14
User entered 'Contact Made (CONTACT MADE)'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:57:44

US3582102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:24:14
User entered empty.	Stephanie Pimienta (b) (4)	25 Nov 2020 19:57:44

US3582102

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:20:33
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	30 Dec 2020 17:28:04

US3582102

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 07:19:12
User entered 'l'	System	30 Dec 2020 17:28:04

US3582102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:20:38
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	30 Dec 2020 17:28:13

US3582102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:20:38
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '29 Dec 2020'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	30 Dec 2020 17:28:13

US3582102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:20:38
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Roxanne Erolin (b) (4) (b) (4)	30 Dec 2020 17:28:13

US3582102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:20:38
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Roxanne Erolin (b) (4) (b) (4)	30 Dec 2020 17:28:13

US3582102

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:28
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	29 Jan 2021 01:17:57

US3582102

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User entered 'l'	System	29 Jan 2021 01:17:57

US3582102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:35
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	29 Jan 2021 01:18:12

US3582102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:35
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '26 Jan 2021'	(b) (4) Stephanie Pimienta (b) (4)	29 Jan 2021 01:18:12

US3582102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:35
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered 'Contact Made (CONTACT MADE)'	Stephanie Pimienta (b) (4)	29 Jan 2021 01:18:12

US3582102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:35
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Jan 2021 01:18:12

US3582102

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:41
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	19 Feb 2021 22:09:30

US3582102

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User entered 'l'	System	19 Feb 2021 22:09:30

US3582102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:49
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:19:06

US3582102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:49
User entered '25 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:19:06

US3582102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:49
User entered 'Contact Made (CONTACT MADE)'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:19:06

US3582102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:49
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:19:06

US3582102

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:09:28
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	26 Feb 2021 19:19:16

US3582102

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:29:21
User entered 'l'	System	26 Feb 2021 19:19:16

US3582102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:14:51
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:44

US3582102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:14:51
User entered '16 Mar 2021'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:44

US3582102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[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 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:14:51
User entered 'Clinic (Clinic)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:44

US3582102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'VISIT4'	System	17 Mar 2021 19:27:44

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:28
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:32:33
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
User entered empty.	Stephanie Pimienta (b) (4) (b) (4)	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered empty.	System	29 Mar 2021 22:17:30

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09

US3582102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09

US3582102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:26
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:51

US3582102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:26
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:51

US3582102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:33
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:28:04

US3582102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:33
User entered '16 Mar 2021'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:28:04

US3582102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:33
User entered '13:45'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:28:04

US3582102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered '16 Mar 2021 13:45'	System	17 Mar 2021 19:28:04

US3582102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:15:37
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:28:09

US3582102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:04:09
User entered 'I'	System	17 Mar 2021 19:28:09

US3582102

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:55
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 21:51:26

US3582102

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:55
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '13 Jan 2021'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 21:51:26

US3582102

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:21:55
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Clinic (Clinic)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 21:51:26

US3582102

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

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 21:51:26

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:09:58
DataPoint Un-verified.	Lynn Gross (b) (4)	25 Feb 2021 18:18:19
Signature has been broken.	Lynn Gross (b) (4)	25 Feb 2021 18:18:19
User entered '13 Jan 2021' reason for change: New Information	Lynn Gross (b) (4)	25 Feb 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered '06 Jan 2021' reason for change: Data Entry Error	Stephanie Pimienta (b) (4)	15 Jan 2021 22:13:23
User entered '13 Jan 2021'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:39:39

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:39:39

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '13 Jan 2021'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Placebo (Placebo)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:02:48
User entered 'Placebo (Placebo)'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:02:48
User entered 'Placebo (Placebo)'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:23:06
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User closed query "Will participant receive mRNA-1273?" is missing. Please reconcile.' (Site from System).	System	15 Jan 2021 22:35:44
Query "Will participant receive mRNA-1273?" is missing. Please reconcile.' answered by data change (Site from System).	System	15 Jan 2021 22:35:44
User entered 'Yes (Y)' reason for change: New Information	Stephanie Pimienta (b) (4)	15 Jan 2021 22:35:44
User opened query "Will participant receive mRNA-1273?" is missing. Please reconcile.' (Site from System).	System	15 Jan 2021 22:02:28
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'I'	System	15 Jan 2021 22:02:28

US3582102

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

Form: Unblinding

Generated On: 10 Jun 2021 08:17:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'I'	System	15 Jan 2021 22:35:44
User entered empty.	System	15 Jan 2021 22:02:28

US3582102

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:15
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:27
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:47
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:12
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:17
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:29
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:49
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:30
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	15 Jan 2021 22:38:30
DataPoint set to visible.	System	15 Jan 2021 22:35:44

US3582102

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:15
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:27
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:47
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:12
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:17
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:29
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:49
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:30
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	15 Jan 2021 22:38:30
DataPoint set to visible.	System	15 Jan 2021 22:35:44

US3582102

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User accepted default value 'Pre-Dose (PREDOSE)'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	22 Jan 2021 22:34:29
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	22 Jan 2021 22:33:56
User entered 'No (N)' reason for change: New Information	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:33:56
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Maya Dunstan (b) (4)	22 Jan 2021 22:34:29
	(b) (4)	
User entered '13 Jan 2021'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '13:13'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	22 Jan 2021 22:34:29
User entered '13 Jan 2021 13:13'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '97.4' F	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered 'Other (Other)'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered 'temporal'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '67'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	22 Jan 2021 22:34:29
User entered 'bpm'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '12'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	22 Jan 2021 22:34:29
User entered 'breaths/min'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '130'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	22 Jan 2021 22:34:29
User entered 'mmHg'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty; reason for change Data Entry Error	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:29
User entered '61'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	22 Jan 2021 22:34:29
User entered 'mmHg'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:15
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:27
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:47
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:12
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:17
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 19:41:29
Query 'Please enter data.' answered with 'Not done' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:49
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:23:38
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:24:30
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered empty.	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	15 Jan 2021 22:38:30
DataPoint set to visible.	System	15 Jan 2021 22:35:44

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User accepted default value 'Post-Dose (POSTDOSE)'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:27
User closed query 'Please verify date. Per source, 14Jan21 date documented.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 03:14:39
Query 'Please verify date. Per source, 14Jan21 date documented.' answered with 'post dose vitals documented in source as 14Jan21' (Site from CRA).	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:25:12
Signature has been broken.	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:24:51
User entered '14 Jan 2021' reason for change: Data Entry Error	Paula Lins (b) (4) (b) (4)	18 Feb 2021 22:24:51
User opened query 'Please verify date. Per source, 14Jan21 date documented.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:32:46
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 01:32:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 18:11:36
User entered '13 Jan 2021' reason for change: Per Query Resolution	Lynn Gross (b) (4)	08 Feb 2021 18:11:36
Comment added 'Part 1 of OL-D1 and Vaccination occurred on different days.'	Paula Lins (b) (4) (b) (4)	28 Jan 2021 19:44:21
Comment added 'confirmed, unblinding visit and injection visit were on different dates'.	Maya Dunstan (b) (4) (b) (4)	22 Jan 2021 22:34:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:38:30
User entered '14 Jan 2021'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '11:45'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '14 Jan 2021 11:45'	System	18 Feb 2021 22:24:51
User entered '13 Jan 2021 11:45'	System	08 Feb 2021 18:11:36
User entered '14 Jan 2021 11:45'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '99.1' F	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Other (Other)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'temporal'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '51'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'bpm'	System	15 Jan 2021 22:38:30

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '16'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'breaths/min'	System	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '109'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:24:09
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 07:23:30
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Melissa Scheer (b) (4) (b) (4)	20 Jan 2021 19:23:02
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Jan 2021 22:38:30
User entered '54'	Stephanie Pimienta (b) (4) (b) (4)	15 Jan 2021 22:38:30

US3582102

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	15 Jan 2021 22:38:30

US3582102

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:12
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:11

US3582102

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'Please verify. Per source, 14Jan21 was documented.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 21:29:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 21:29:36
Query 'Please verify. Per source, 14Jan21 was documented.' answered with 'data entry error corrected' (Site from CRA).	Paula Lins (b) (4)	16 Mar 2021 20:20:35
User entered '14 Jan 2021' reason for change: Data Entry Error	Paula Lins (b) (4)	16 Mar 2021 20:20:26
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:14:23
User opened query 'Please verify. Per source, 14Jan21 was documented.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:13:27
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:10:36
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Feb 2021 18:34:19
DataPoint Un-verified.	Paula Lins (b) (4)	24 Feb 2021 18:34:19
User entered '22 Jan 2021' reason for change: Data Entry Error	Paula Lins (b) (4)	24 Feb 2021 18:34:19
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:12
Comment added 'this is correct . screening and randomization on different days'.	Lynn Gross (b) (4)	08 Feb 2021 18:13:11
Comment added 'Physical exam date was same date as immunization'.	Paula Lins (b) (4)	28 Jan 2021 19:45:37
Comment added 'confirmed, unblinding visit and injection visit were on different dates'.	Maya Dunstan (b) (4)	22 Jan 2021 22:29:49
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:42:11
User entered '14 Jan 2021'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:11

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

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)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mRNA-1273'	System	15 Jan 2021 22:42:51
DataPoint set to visible.	System	15 Jan 2021 22:35:44

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 07:16:52
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'confirmed, unblinding visit and injection visit were on different dates' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 22:30:58
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:42:51
User entered '14 Jan 2021'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '11:14'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '14 Jan 2021 11:14'	System	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:39
User entered 'ONCE'	System	15 Jan 2021 22:42:51

US3582102

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

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 22:42:51

US3582102

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:52
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:03:45

US3582102

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:52
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	15 Jan 2021 22:05:09
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	15 Jan 2021 22:05:09
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:05:09
User closed query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:05:09
User entered '13 Jan 2021' reason for change: Data Entry Error	Stephanie Pimienta (b) (4)	15 Jan 2021 22:05:09
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:03:45
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:03:45
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:03:45
User entered '13 Jan 2020'	Stephanie Pimienta (b) (4)	15 Jan 2021 22:03:45

US3582102

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:52
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '13:21'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:03:45

US3582102

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '13 Jan 2021 13:21'	System	15 Jan 2021 22:05:09
User entered '13 Jan 2020 13:21'	System	15 Jan 2021 22:03:45

US3582102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:56
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:05:38

US3582102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:56
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '13 Jan 2021'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:05:38

US3582102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:33:56
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '13:23'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 22:05:38

US3582102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '13 Jan 2021 13:23'	System	15 Jan 2021 22:05:38

US3582102

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	22 Jan 2021 21:15:14

US3582102

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

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'I'	System	22 Jan 2021 21:15:14

US3582102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:08
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	22 Jan 2021 21:15:31

US3582102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:08
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered '21 Jan 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	22 Jan 2021 21:15:31

US3582102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:08
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:29
User entered 'Contact Made (CONTACT MADE)'	Marilyn Nguyen (b) (4) (b) (4)	22 Jan 2021 21:15:31

US3582102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:08
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:29
User entered empty.	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	22 Jan 2021 21:15:31

US3582102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:22
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:06:48

US3582102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'l'	System	08 Feb 2021 23:06:48

US3582102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'I'	System	08 Feb 2021 23:06:48
DataPoint set to visible.	System	08 Feb 2021 23:06:48

US3582102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:26
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:07:03

US3582102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:26
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '08 Feb 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:07:03

US3582102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:26
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Clinic (Clinic)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:07:03

US3582102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'OLD29'	System	08 Feb 2021 23:07:03

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User accepted default value 'Pre-Dose (PREDOSE)'	Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '08 Feb 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '09:44'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '08 Feb 2021 09:44'	System	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '97.3' F	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Other (Other)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Temporal'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '73'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'bpm'	System	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '12'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'breaths/min'	System	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '148'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '69'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	08 Feb 2021 23:08:06

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User accepted default value 'Post-Dose (POSTDOSE)'	Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '08 Feb 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '10:31'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '08 Feb 2021 10:31'	System	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '97.6' F	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Other (Other)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Temporal'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '61'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'bpm'	System	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '10'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'breaths/min'	System	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '136'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:34:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '62'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mmHg'	System	08 Feb 2021 23:09:01

US3582102

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:14
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:17

US3582102

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:14
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '08 Feb 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:17

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

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)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'mRNA-1273'	System	08 Feb 2021 23:09:41
DataPoint set to visible.	System	08 Feb 2021 23:06:48

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '08 Feb 2021'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '10:01'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '08 Feb 2021 10:01'	System	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Marilyn Nguyen (b) (4) (b) (4)	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:17
User entered 'ONCE'	System	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 23:09:41

US3582102

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:32
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:36

US3582102

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'l'	System	17 Feb 2021 21:16:36

US3582102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:36
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:46

US3582102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:36
User entered '16 Feb 2021'	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:46

US3582102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:36
User entered 'Contact Made (CONTACT MADE)'	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:46

US3582102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:36
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:46

US3582102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:28
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 01:35:38
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Feb 2021 21:16:54

US3582102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'l'	System	17 Feb 2021 21:16:54

US3582102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
User closed query 'Please complete next page, VS done- y/n. Per source, no data documented.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 22:58:48
Query 'Please complete next page, VS done- y/n. Per Stella Lee source, no data documented.' answered with 'done' (Site from CRA).	(b) (4)	29 Mar 2021 16:50:25
User opened query 'Please complete next page, VS done- y/n. Per source, no data documented.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 22:20:11
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:16:02
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:26:50

US3582102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:16:02
User entered '16 Mar 2021'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:26:50

US3582102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:16:02
User entered 'Clinic (Clinic)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:26:50

US3582102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered 'OLD57'	System	17 Mar 2021 19:26:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 22:58:58
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	26 Mar 2021 21:20:50

US3582102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered empty.	System	26 Mar 2021 21:20:50

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22

US3582102

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:20:16
User entered 'No (N)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:01

US3582102

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:20:16
User entered empty.	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:01

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:20:21
User entered 'Yes (Y)'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:14

US3582102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:20:21
User entered '16 Mar 2021'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:14

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:20:21
User entered '13:45'	Roxanne Erolin (b) (4) (b) (4)	17 Mar 2021 19:27:14

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:13:22
User entered '16 Mar 2021 13:45'	System	17 Mar 2021 19:27:14

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:17:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:16
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4)	
	V1 Iran (b) (4)	22 Dec 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:30
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Chipped tooth - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 20:37:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 20:37:15
Data point term sent to Coder	System	30 Mar 2021 17:54:37
User closed query 'For coding purposes, please split Chipped teeth and Laceration to gingiva onto separate log lines to enable coding. Thank you.' (Site from System).	System	30 Mar 2021 17:54:28
Query 'For coding purposes, please split Chipped teeth and Laceration to gingiva onto separate log lines to enable coding. Thank you.' answered with 'per query resolution, Chipped teeth and Laceration to gingiva onto separate log lines' (Site from System).	Paula Lins (b) (4)	30 Mar 2021 17:54:28
DataPoint Un-verified.	Paula Lins (b) (4)	30 Mar 2021 17:53:41
Coding entries removed.	Paula Lins (b) (4)	30 Mar 2021 17:53:41
User entered 'CHIPPED TEETH' reason for change: Per Query Resolution	Paula Lins (b) (4)	30 Mar 2021 17:53:41
User opened query 'For coding purposes, please split Chipped teeth and Laceration to gingiva onto separate log lines to enable coding. Thank you.' (Site from System).	Coder Import (b) (4)	26 Mar 2021 02:12:37
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Chipped tooth - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 16:29:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 16:29:29
Data point term sent to Coder	System	22 Dec 2020 23:42:57

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'chipped teeth and laceration to gingiva'	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Yes (Y)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'No (N)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '12 Dec 2020' reason for change: Data Entry Error	Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:46:49
User entered '15 Dec 2020'	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User entered empty.	System	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 17:47:03
User entered 'No (N)' reason for change: New Information	Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:47:03
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 17:46:49
User entered 'Yes (Y)'	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
User closed query 'Please verify date. Per source 22Dec2020 is documented.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 17:53:10
Query 'Please verify date. Per source 22Dec2020 is documented.' answered with 'verified and accurate' (Site from CRA).	Lynn Gross (b) (4)	24 Feb 2021 18:45:57
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User opened query 'Please verify date. Per source 22Dec2020 is documented.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 17:42:23
User entered '20 Dec 2020' reason for change: New Information	Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:46:49
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User entered empty.	System	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'No (N)'	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

US3582102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Related (NOT RELATED)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Applicable (NOT APPLICABLE)'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'l'	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '1' reason for change: New Information	Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:46:49
User entered '0'	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 17:46:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 17:46:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:46:49
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 23:42:02
User entered empty.	Vi Tran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	V1 Iran (b) (4) (b) (4)	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User entered '0'	System	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13
User entered 'I'	System	22 Dec 2020 23:42:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia aggravated - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 10:38:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 10:38:09
Data point term sent to Coder	System	15 Jan 2021 20:23:17
Coding entries removed.	Stephanie Pimienta (b) (4)	15 Jan 2021 20:22:40
User entered 'ANEMIA exacerbation' reason for change: New Information	Stephanie Pimienta (b) (4)	15 Jan 2021 20:22:40
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	05 Jan 2021 21:53:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Jan 2021 21:53:42
Data point term sent to Coder	System	05 Jan 2021 21:53:12
User entered 'Anemia'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'No (N)'	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'No (N)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '29 Dec 2020'	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User entered empty.	System	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:15:12
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Feb 2021 18:43:27
DataPoint Un-verified.	Lynn Gross (b) (4)	24 Feb 2021 18:43:27
User entered 'No (N)' reason for change: Data Entry Error	Lynn Gross (b) (4)	24 Feb 2021 18:43:27
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Feb 2021 18:43:10
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 18:14:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 18:14:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Lynn Gross (b) (4)	08 Feb 2021 18:14:30
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:52:36
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:43:10
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	24 Feb 2021 18:43:10
DataPoint Un-verified.	Lynn Gross (b) (4)	24 Feb 2021 18:43:10
User entered '21 Feb 2021' reason for change: Data Entry Error	Lynn Gross (b) (4)	24 Feb 2021 18:43:10
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:42:46
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User entered empty.	System	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 23:29:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 23:29:16
User entered 'No (N)' reason for change: Data Entry Error	Stephanie Pimienta (b) (4)	05 Jan 2021 23:29:16
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:52:36
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Related (NOT RELATED)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Related (NOT RELATED)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered 'Not Applicable (NOT APPLICABLE)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User closed query ' <input type="checkbox"/> Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field once data is available.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 08:23:40
Query ' <input type="checkbox"/> Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field once data is available.' answered with 'Updated, per query' (Site from DM).	Jana ffitich (b) (4) (b) (4)	16 Feb 2021 22:29:52
User entered '0' reason for change: Data Entry Error	Jana ffitich (b) (4) (b) (4)	16 Feb 2021 22:29:35
User opened query ' <input type="checkbox"/> Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field once data is available.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 04:31:19
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field. (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 04:31:19
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'reevaluation pending' (Site from DM).	Lynn Gross (b) (4)	08 Feb 2021 18:15:36
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#18) recorded that matches this AE during this timeframe. Please review and update this field. (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 05:41:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

None

Audit	User	Time (GMT)
User entered 'l'	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered '1' reason for change: Per Query Resolution	Jana Hitch (b) (4) (b) (4)	16 Feb 2021 22:29:35
User entered '0'	Stephanie Pimienta (b) (4) (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	8 Feb 2021 17:45:44
User entered '0'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:17:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Lynn Gross (b) (4)	24 Feb 2021 18:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:45:51
DataPoint Verified.		18 Feb 2021 17:45:44
User closed query 'Data is required. Please complete.' (Site from System).		08 Feb 2021 18:15:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 18:15:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Lynn Gross (b) (4)	08 Feb 2021 18:15:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:52:36
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:44
User entered empty.	Stephanie Pimienta (b) (4)	05 Jan 2021 21:52:36

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User entered '0'	System	05 Jan 2021 23:29:16

US3582102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18
User entered 'I'		05 Jan 2021 21:52:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:20:00
User entered	System	25 Feb 2021 12:19:56
'USA-US124-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 12:19:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Middle cerebral artery stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 22:57:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 22:57:56
Data point term sent to Coder	System	24 Feb 2021 17:19:10
User entered 'Acute left middle cerebral artery stroke'	Jana ffitch (b) (4) (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Yes (Y)'	Jana ffitch (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Jana ffitch (b) (4) (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Jana ffitch (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered '21 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:19:13
	Jana ffitch (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Jana ffitch (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Jana ffitch (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'PV query: Please consider updating event outcome to resolved on 22 Feb 2021 based on normal speech noted at hospital discharge.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 14:15:34
Query 'PV query: Please consider updating event outcome to resolved on 22 Feb 2021 based on normal speech noted at hospital discharge.' answered with 'for clarification: Date of AE resolution 21FEB2021 is correct as there was no progression of stroke/stroke symptoms from time of admission. ' (Site from Safety).	Paula Lins (b) (4)	30 Mar 2021 19:39:08
User opened query 'PV query: Please consider updating event outcome to resolved on 22 Feb 2021 based on normal speech noted at hospital discharge.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 12:12:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '21 Feb 2021'	Jana Htich (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Yes (Y)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

US3582102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 17:18:24
	Jana Htich (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '21 Feb 2021'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:07:32
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records faxed.' (Site from Safety).	Roxanne Erolin (b) (4)	12 Mar 2021 18:46:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:16:40
User entered '22 Feb 2021'	Jana ffitch (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Related (NOT RELATED)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Related (NOT RELATED)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Applicable (NOT APPLICABLE)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

None

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:21:40
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:21:02
User closed query 'PV Query: Please provide the date that Warfarin was stopped/interrupted prior to event.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:07:38
Query 'PV Query: Please provide the date that Warfarin was stopped/interrupted prior to event.' answered with 'Please see concomitant medication #1. Coumadin was stopped 13FEB2021. ' (Site from Safety).	Maya Dunstan (b) (4) (b) (4)	15 Mar 2021 22:08:56
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User opened query 'PV Query: Please provide the date that Warfarin was stopped/interrupted prior to event.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:16:11
User entered 'I'	Jana ffitch (b) (4) (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:04:27
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'for clarification: there were multiple diagnostic Con-procedures which are documented in source and database. There were no therapeutic Con Procedures for this event.' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 18:35:13
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:21:16
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)	16 Mar 2021 14:07:41
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 'Please see discharge summary faxed on 12MAR2021.' (Site from Safety).	Maya Dunstan (b) (4)	15 Mar 2021 22:08:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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). User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 16:15:46
	Jana ffitich (b) (4) (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Aphasia'	Jana Htich (b) (4)	24 Feb 2021 17:18:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'PV Query: Please confirm if a follow-up CT scan was done and provide the results.' (Site from Safety).	(b) (4)	01 Apr 2021 11:51:56
Query 'PV Query: Please confirm if a follow-up CT scan was done and provide the results.' answered with 'Per Query: follow-up CT was cancelled by health care provider. Determined unnecessary. This procedure will not occur.' (Site from Safety).	Paula Lins (b) (4)	31 Mar 2021 22:25:13
User opened query 'PV Query: Please confirm if a follow-up CT scan was done and provide the results.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 12:11:38
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)	16 Mar 2021 14:07:45
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)	16 Mar 2021 14:07:43
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 'COVID-19 testing not done.' (Site from Safety).	Maya Dunstan (b) (4)	15 Mar 2021 22:10:04
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 'Medications have been added.' (Site from Safety).	Maya Dunstan (b) (4)	15 Mar 2021 22:09:48
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

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)	04 Mar 2021 16:15:25
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).		04 Mar 2021 16:15:00
User entered 'Participant woke on 2/21/21 with expressive and receptive aphasia. He was admitted to Swedish Hospital and diagnosed with acute left middle cerebral artery stroke with M3, M4 distribution and improving. Participant discharged on 2/22/21 to home. Stroke thought to be cardioembolic due to being off his Warfarin for his colonoscopy and endoscopy on 2/18/21.'	Jana ffitich (b) (4) (b) (4)	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 17:18:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Cortical dysfunction NEC, PT: Aphasia, LLT: Aphasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:57:48
Data point term sent to Coder	System	02 Mar 2021 23:56:49
User entered 'Aphasia'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered '21 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 17:19:13
	Marilyn Nguyen (b) (4)	02 Mar 2021 23:55:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Yes (Y)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
	Marilyn Nguyen (b) (4)	02 Mar 2021 23:55:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
	Marilyn Nguyen (b) (4)	02 Mar 2021 23:55:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:19:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	02 Mar 2021 23:55:56
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Related (NOT RELATED)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Related (NOT RELATED)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'Not Applicable (NOT APPLICABLE)'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered 'l'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	18 Mar 2021 22:11:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 23:04:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 23:04:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Lynn Gross (b) (4)	04 Mar 2021 23:04:09
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:21:04
DataPoint Verified.		04 Mar 2021 17:19:13
User opened query 'Data is required. Please complete.' (Site from System).		02 Mar 2021 23:55:56
User entered empty.	Marilyn Nguyen (b) (4)	02 Mar 2021 23:55:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:19:13
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	02 Mar 2021 23:55:56

US3582102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 23:55:56

US3582102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 23:55:56

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Gingival injury, LLT: Gingival injury - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 06:48:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 06:48:21
Data point term sent to Coder	System	30 Mar 2021 17:56:39
User entered 'Laceration to Gingiva'	Paula Lins (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Yes (Y)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '12 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
User entered empty.	System	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '22 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4)	
	Paula Lins (b) (4)	30 Mar 2021 17:56:07
	(b) (4)	

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
User entered empty.		30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.		15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Paula Lins (b) (4)	30 Mar 2021 17:56:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'l'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	10 Apr 2021 18:30:49
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:46:10
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated, not con procedures associated' (Site from DM).	Melissa Scheer (b) (4)	06 Apr 2021 23:23:25
Signature has been broken.	Melissa Scheer (b) (4)	06 Apr 2021 23:22:53
User entered '0' reason for change: Per Query Resolution	Melissa Scheer (b) (4)	06 Apr 2021 23:22:53
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 04:27:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered '1'	Paula Lins (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:31:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
User entered '0'		30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29
User entered 'I'	System	30 Mar 2021 17:56:07

US3582102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:56:29

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:17:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:22
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:11
User entered 'Yes (Y)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:04:30

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:16:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:16:51
Data point term sent to Coder	System	08 Sep 2020 22:16:19
Coding entries removed.	Barbara Carste (b) (4)	08 Sep 2020 22:15:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:07:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:07:55
Data point term sent to Coder	System	08 Sep 2020 22:06:55
User entered 'Coumadin'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'ATRIAL FLUTTER AND ventricular SEPTAL DEFECT' reason for change: Data Entry Error	Barbara Carste (b) (4)	08 Sep 2020 22:15:22
User entered 'atrial flutter and septal defect'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered '7.5 or 5'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '7.5mg M/W/F and 5mg all other days'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '15 Nov 2008'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:36:02
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:36:02
Signature has been broken.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:22:33
User entered 'No (N)' reason for change: New Information	(b) (4)	26 Feb 2021 19:22:33
User signature succeeded.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:22:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:22:33
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
	(b) (4)	19 Nov 2020 23:50:24
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
	Barbara Carste (b) (4)	08 Sep 2020 22:06:13
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:36:04
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:36:04
Signature has been broken.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:22:33
User entered '13 Feb 2021' reason for change: New Information	(b) (4)	26 Feb 2021 19:22:33
User signature succeeded.	Marilyn Nguyen (b) (4)	26 Feb 2021 19:22:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:22:33
User entered empty.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
	(b) (4)	19 Nov 2020 23:50:24
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
	Barbara Carste (b) (4)	08 Sep 2020 22:06:13
	(b) (4)	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:06:13
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User entered 'I'	System	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User entered '1'	System	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:50
User entered '804 (804)'	System	08 Sep 2020 22:06:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: CAPILLARY STABILIZING AGENTS, ATC: BIOFLAVONOIDS, PRODUCT: DIOSMIN, PRODUCTSYNONYM: DIH - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 00:40:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 00:40:00
Data point term sent to Coder	System	08 Sep 2020 22:09:01
User entered 'DiH-XR'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'atrial flutter'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '120'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:08:25

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:08:25

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '09 Apr 2005'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:08:25
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:08:25

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:08:25

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:08:25

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:09:49
Data point term sent to Coder User entered 'lipitor'	System Barbara Carste (b) (4)	08 Sep 2020 22:09:04 08 Sep 2020 22:09:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'hyperlipidemia'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '10'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:09:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '14 Dec 2015'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:03
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:09:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:09:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:09:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM, PRODUCTSYNONYM: COZAAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:10:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:10:50
Data point term sent to Coder User entered 'cozaar'	System Barbara Carste (b) (4)	08 Sep 2020 22:10:06 08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'hypertension'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '100'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:09:46

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '29 Sep 2009'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:09:46
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:09:46
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:09:46

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:09:46

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:09:46

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:12:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:12:43
Data point term sent to Coder Coding entries removed.	System Barbara Carste (b) (4)	11 Sep 2020 22:11:51 11 Sep 2020 22:11:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 23:52:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:52:02
Data point term sent to Coder User entered 'allopurinol'	System Barbara Carste (b) (4)	08 Sep 2020 22:11:07 08 Sep 2020 22:10:45

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'kidney stones'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '100'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:10:45

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'twice daily (BID)'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:11:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:11:49
User entered 'Oral (ORAL)' reason for change: New Information	Barbara Carste (b) (4)	11 Sep 2020 22:11:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:10:45
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '07 Apr 1997'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:10:45
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 22:10:45

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:10:45

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:10:45

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST, PRODUCTSYNONYM: XALATAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Jan 2021 08:39:00
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 08:39:00
Data point term sent to Coder	System	19 Jan 2021 21:30:33
Coding entries removed.	Maya Dunstan (b) (4) (b) (4)	19 Jan 2021 21:30:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST, PRODUCTSYNONYM: XALATAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:54:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:54:37
Data point term sent to Coder	System	08 Sep 2020 22:15:16
User entered 'XALATAN EYE DROPS .005%' reason for change: Data Entry Error	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:14:53
Data point term sent to Coder	System	08 Sep 2020 22:13:11
User entered 'xalatan eye drops'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:12:20

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'open angle glaucoma'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'l'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Other (OTHER)'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'drop both eyes'	(b) (4), (b) (6)	08 Sep 2020 22:12:20
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:13:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:13:12
User entered 'once daily (QD)' reason for change: New Information	Barbara Carste (b) (4)	11 Sep 2020 22:13:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:12:20
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Other (OTHER)'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Un-verified.	(b) (4)	
	Maya Dunstan (b) (4)	19 Jan 2021 21:30:02
User entered 'OPHTHALMIC' reason for change:	(b) (4)	
Data Entry Error	Maya Dunstan (b) (4)	19 Jan 2021 21:30:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'ophthalmic'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '01 Oct 2018'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:12:20
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 22:13:12
User entered empty.	System	08 Sep 2020 22:12:20

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Sep 2020 22:13:12
User entered empty.	System	08 Sep 2020 22:12:20

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:13:12
User entered empty.	System	08 Sep 2020 22:12:20

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
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)	08 Sep 2020 22:19:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:19:50
Data point term sent to Coder User entered 'lasix'	System Barbara Carste (b) (4)	08 Sep 2020 22:19:25 08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'heart failure'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '80'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '14 Dec 2015'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:18:37
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:18:37

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-TAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:28:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:28:38
Data point term sent to Coder	System	08 Sep 2020 22:20:25
User entered 'k-tab'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'hypokalemia'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '20'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Other (OTHER)'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'MEq'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '24 Feb 2020'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:19:31
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:19:31

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:19:31

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:19:31

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:19:31

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:21:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:21:54
Data point term sent to Coder	System	08 Sep 2020 22:21:26
User entered 'PriLOSEC'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'reflux'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '10'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'mg (mg)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'once daily (QD)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:20:27

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:20:27

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '25 Nov 2003'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:20:27
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:20:27
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:20:27

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:20:27

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:20:27

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:27:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:27:47
Data point term sent to Coder	System	08 Sep 2020 22:22:27
User entered 'ketoconazole shampoo 2%'	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:21:41

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'seborrheic dermatitis'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'l'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Other (OTHER)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'application'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'every month (QM)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Topical (TOPICAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'un UNK 2013'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:21:41
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 22:21:41

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:21:41

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	08 Sep 2020 22:21:41

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM WITH D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 22:24:51
Data point term sent to Coder	System	08 Sep 2020 22:23:29
User entered 'calcium with D3'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'health maintenance'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
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.	(b) (4), (b) (6)	16 Oct 2020 04:51:05
' (Site from DM).		
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.	Barbara Carste (b) (4)	14 Oct 2020 20:23:41
' answered with 'Per PI not clinically relevant' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	05 Oct 2020 10:58:59
' (Site from DM).		
User entered 'I'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'tablet (TABLET)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:22:38
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'twice daily (BID)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:22:38

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Un UNK 2015'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:22:38
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 22:22:38

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:22:38

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:22:38

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 15:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 15:00:42
Data point term sent to Coder	System	17 Sep 2020 19:43:46
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	17 Sep 2020 19:43:41
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'ingredients added to name of medication.' (Site from System).	Joyce Benoit (b) (4)	17 Sep 2020 19:43:41
Data point term sent to Coder	System	17 Sep 2020 19:40:37
User entered 'PROSTATE PLUS HEALTH COMPLEX: Saw palmetto, zinc gluconate, pumpkin seed oil, sunflower seed oil' reason for change: Per Query Resolution	Joyce Benoit (b) (4)	17 Sep 2020 19:39:42
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	14 Sep 2020 13:00:39
Data point term sent to Coder	System	08 Sep 2020 22:24:30
User entered 'prostate plus health complex'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'benign prostatic hyperplasia'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:14:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:14:00
User entered '1' reason for change: Data Entry Error	Barbara Carste (b) (4)	11 Sep 2020 22:14:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:24:11
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'tablet (TABLET)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'twice daily (BID)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4) (b) (4)	08 Sep 2020 22:24:11

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:46:38
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'Reviewed and reconciled' (Site from DM).	Roxanne Erolin (b) (4)	13 Oct 2020 22:44:04
	(b) (4)	
User entered 'UN UNK 2015' reason for change: New Information	Roxanne Erolin (b) (4)	13 Oct 2020 22:43:35
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:59:09
User entered 'UN UNK 2010'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:24:11
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 22:24:11

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:24:11

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:24:11

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 01:09:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 01:09:58
Data point term sent to Coder	System	08 Sep 2020 22:25:31
User entered 'ibuprofen'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	19 Nov 2020 23:50:24
User entered 'stiffness in back, shoulders, hips, knees'	(b) (4), (b) (6)	08 Sep 2020 22:25:05
	Barbara Carste (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '400'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:14:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:14:22
User entered 'mg (mg)' reason for change: Data Entry Error	Barbara Carste (b) (4)	11 Sep 2020 22:14:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:25:05
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'as needed (PRN)'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Oral (ORAL)'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'UN UNK 1995'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered '0'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'Yes (Y)'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered empty.	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 23:50:24
User entered 'No (N)'	Barbara Carste (b) (4)	08 Sep 2020 22:25:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 22:25:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 22:25:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 22:25:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 22:26:59
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)	25 Nov 2020 20:00:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 20:00:13
Data point term sent to Coder	System	25 Nov 2020 19:59:49
User entered 'influenza vaccine'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 22:26:59
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered 'health maintenance'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 22:26:59
User entered '0.5'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	07 Dec 2020 22:26:59
User entered 'Intramuscular (INTRAMUSCULAR)'	Stephanie Pimienta (b) (4)	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered '31 Oct 2020'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 23:18:12
DataPoint Un-verified.	Melissa Scheer (b) (4)	17 Dec 2020 23:18:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Melissa Scheer (b) (4)	17 Dec 2020 23:18:12
	(b) (4), (b) (6)	07 Dec 2020 22:26:59
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 19:59:35
User entered empty.	Stephanie Pimienta (b) (4)	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered '31 Oct 2020'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
DataPoint Verified.	(b) (4)	07 Dec 2020 22:26:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 19:59:35
	Stephanie Pimienta (b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User entered empty.	System	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User entered empty.	System	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:57
User entered empty.	System	25 Nov 2020 19:59:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 18:53:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 18:53:20
Data point term sent to Coder	System	29 Dec 2020 18:35:14
User entered 'Amoxicillin'	Paula Lins (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Chipped Teeth and laceration to gingiva'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '500'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'mg (mg)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'Please verify. Per source "4x/d" is marked.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 17:53:32
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:53:30
Query 'Please verify. Per source "4x/d" is marked.' answered with 'updated' (Site from CRA).	Lynn Gross (b) (4)	25 Feb 2021 18:37:06
Signature has been broken.	Lynn Gross (b) (4)	25 Feb 2021 18:36:59
User entered 'four times daily (QID)' reason for change: Data Entry Error	Lynn Gross (b) (4)	25 Feb 2021 18:36:59
User opened query 'Please verify. Per source "4x/d" is marked.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 17:55:32
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'three times daily (TID)'	Paula Lins (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Oral (ORAL)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '15 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '22 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
User entered '4'	System	25 Feb 2021 18:36:59
User entered '3'	System	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
User entered '1'	System	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:07
User entered '804 (804)'	System	29 Dec 2020 18:35:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:39:25
Data point term sent to Coder	System	29 Dec 2020 18:37:15
User entered 'Chlorhexidine Gluconate 0.12%'	Paula Lins (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Chipped teeth and laceration to gingiva'	(b) (4)	
	Paula Lins (b) (4)	29 Dec 2020 18:36:32
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '5'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'mL (mL)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'three times daily (TID)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Other (OTHER)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'oral rinse (and spit)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '15 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '0'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '22 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
User entered '3'	System	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
User entered 'I'	System	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:14
User entered '804 (804)'	System	29 Dec 2020 18:36:32

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: IRON [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Jan 2021 20:41:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Jan 2021 20:41:51
Data point term sent to Coder	System	15 Jan 2021 20:25:19
User entered '(iron) ferrous sulfate'	Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'anemia'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '325'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'mg (mg)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'once daily (QD)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Oral (ORAL)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '24 Mar 2017'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '0'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	01 Apr 2021 16:38:17
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:38:17
Signature has been broken.	Paula Lins (b) (4)	30 Mar 2021 22:05:49
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 22:05:49
DataPoint Verified.	Paula Lins (b) (4)	30 Mar 2021 22:05:49
User signature succeeded.	(b) (4)	30 Mar 2021 22:05:49
User entered '30 Dec 2020'	Paula Lins (b) (4)	30 Mar 2021 22:05:49
	(b) (4)	30 Mar 2021 22:05:49
	(b) (4), (b) (6)	18 Feb 2021 17:55:01
	(b) (4)	18 Feb 2021 17:55:01
	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
	(b) (4)	13 Feb 2021 00:00:17
	Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
User entered 'I'	System	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
User entered '1'	System	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:03
User entered '804 (804)'	System	15 Jan 2021 20:24:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med (IRON) FERROUS SULFATE, # 17 / (Start date24 MAR 2017- Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:05:57
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med (IRON) FERROUS SULFATE, # 17 / (Start date24 MAR 2017- Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'To clarify: Ferrous Sulfate #17 stop date corrected to 29Dec2020. start date of this Ferrous Sulfate #18 is correct. dose was changed. ' (Site from DM).	Paula Lins (b) (4) (b) (4)	30 Mar 2021 22:07:29
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med (IRON) FERROUS SULFATE, # 17 / (Start date24 MAR 2017- Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:07:43
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: IRON [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Jan 2021 20:41:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Jan 2021 20:41:52
Data point term sent to Coder	System	15 Jan 2021 20:26:20
User entered '(iron) ferrous sulfate'	Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

PRODUCTION RELEASE (v12.003
EAB) (1725)

2515 of 2773

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'anemia'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '325'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'mg (mg)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'twice daily (BID)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Oral (ORAL)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User closed query 'Per DM CLR RQ: Note that start date of this ConMed overlaps with Stop date of CM #17. Please review and update dates accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 05:50:26
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
Query 'Per DM CLR RQ: Note that start date of this ConMed overlaps with Stop date of CM #17. Please review and update dates accordingly.' answered with 'updated' (Site from DM).	Lynn Gross (b) (4)	04 Mar 2021 01:17:56
DataPoint Un-verified.	Lynn Gross (b) (4)	04 Mar 2021 01:17:44
Signature has been broken.	Lynn Gross (b) (4)	04 Mar 2021 01:17:44
User entered '29 Dec 2020' reason for change: Data Entry Error	Lynn Gross (b) (4)	04 Mar 2021 01:17:44
User opened query 'Per DM CLR RQ: Note that start date of this ConMed overlaps with Stop date of CM #17. Please review and update dates accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:28:09
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with (IRON) FERROUS SULFATE CM#17 (Start date 24 MAR 2017 - Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:28:09
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with (IRON) FERROUS SULFATE CM#17 (Start date 24 MAR 2017 - Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'dose change on 30/Dec/2020 from 1 tab daily to twice daily' (Site from DM).	Lynn Gross (b) (4)	25 Feb 2021 18:39:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with (IRON) FERROUS SULFATE CM#17 (Start date 24 MAR 2017 - Stop date 30 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:54:29
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 19:24:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Jan 2021 19:24:26
User entered '30 Dec ' (non-conformant).	Melissa Scheer (b) (4)	15 Jan 2021 20:25:57
	(b) (4)	15 Jan 2021 20:25:57
	Stephanie Pimienta (b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '0'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
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) (6)	04 Apr 2021 04:44:59
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 'confirmation medication is still on going. has replaced former chronic dose of same medication and will continue even though AE has resolved. ' (Site from DM).	Paula Lins (b) (4) (b) (4)	31 Mar 2021 22:23:13
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)	17 Mar 2021 12:22:04
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:55:01
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'No (N)'	(b) (4) Stephanie Pimienta (b) (4)	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 20:25:57

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:39:41
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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:07:44
Data point term sent to Coder	System	30 Mar 2021 22:12:30
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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification. ' answered with 'clarification: Medication is associated with AE#2, anemia exacerbation.' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:12:21
Coding entries removed.	Paula Lins (b) (4)	30 Mar 2021 22:11:34
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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:12:29

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:48:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:48:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
Data point term sent to Coder	System	03 Mar 2021 21:54:58
User entered 'Fentanyl'	Marilyn Nguyen (b) (4)	03 Mar 2021 21:54:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	01 Apr 2021 16:37:39
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:37:39
	Paula Lins (b) (4)	30 Mar 2021 22:11:34
User entered 'ANEMIA EXACERBATION' reason	(b) (4)	30 Mar 2021 22:11:34
for change: Data Entry Error	Paula Lins (b) (4)	30 Mar 2021 22:11:34
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Barret's esophagus, Anemia	Marilyn Nguyen (b) (4)	03 Mar 2021 21:54:05
exacerbation, colon polyps'	(b) (4)	03 Mar 2021 21:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '50'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'ug (ug)'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:54:05
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:54:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:41:03
	Marilyn Nguyen (b) (4)	03 Mar 2021 21:54:05
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User entered empty.	System	03 Mar 2021 21:54:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User entered empty.	System	03 Mar 2021 21:54:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:41
User entered empty.	System	03 Mar 2021 21:54:05

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 12:55:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 12:55:23
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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	31 Mar 2021 06:33:44
' (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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification.	Paula Lins (b) (4)	30 Mar 2021 22:17:40
' answered with 'Clarification: medication is associated with AE#2: Anemia Exacerbation' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 22:15:32
Coding entries removed.	Paula Lins (b) (4)	30 Mar 2021 22:14:38
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 BARRET'S ESOPHAGUS, COLON POLYPS should be recorded, and update con med indication or provide clarification.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:13:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:44:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:44:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
Data point term sent to Coder	System	03 Mar 2021 21:55:59
User entered 'Midazolam'	Marilyn Nguyen (b) (4)	03 Mar 2021 21:55:18
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	01 Apr 2021 16:37:24
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 16:37:24
User entered 'ANEMIA EXACERBATION' reason for change: Data Entry Error	Paula Lins (b) (4)	30 Mar 2021 22:14:38
DataPoint Verified.	(b) (4)	30 Mar 2021 22:14:38
User entered 'Barret's esophagus, anemia exacerbation, colon polyps'	Paula Lins (b) (4)	30 Mar 2021 22:14:38
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
	(b) (4)	04 Mar 2021 17:41:03
	Marilyn Nguyen (b) (4)	03 Mar 2021 21:55:18
	(b) (4)	03 Mar 2021 21:55:18

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '3'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:55:18
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User entered empty.	System	03 Mar 2021 21:55:18

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User entered empty.	System	03 Mar 2021 21:55:18

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:36
User entered empty.	System	03 Mar 2021 21:55:18

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
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)	07 Apr 2021 15:52:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:52:41
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
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 BARRET'S ESOPHAGUS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:28:38
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 BARRET'S ESOPHAGUS should be recorded, and update con med indication or provide clarification. ' answered with 'clarification: this medication is associated with AE#2: Anemia Exacerbation' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:19:40
Data point term sent to Coder Coding entries removed.	System Paula Lins (b) (4)	30 Mar 2021 22:18:35 30 Mar 2021 22:18:20
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 BARRET'S ESOPHAGUS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:13:42

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
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)	05 Mar 2021 05:14:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:14:46
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
Data point term sent to Coder	System	03 Mar 2021 21:57:06
User entered 'Lidocaine 4%'	Marilyn Nguyen (b) (4)	03 Mar 2021 21:56:35
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:56:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:37:06
User closed query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:29:25
Query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify.' answered with 'clarification: this medication was Not used as a therapeutic to treat anemia, but for a diagnostic test to evaluate source of anemia.' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:20:27
DataPoint Un-verified.	(b) (4)	30 Mar 2021 22:18:20
User entered 'ANEMIA EXACERBATION' reason for change: Data Entry Error	Paula Lins (b) (4)	30 Mar 2021 22:18:20
User opened query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:56:26
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Barret's esophagus, anemia exacerbation'	Marilyn Nguyen (b) (4)	03 Mar 2021 21:56:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '5'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:56:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:56:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User entered empty.	System	03 Mar 2021 21:56:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User entered empty.	System	03 Mar 2021 21:56:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:37
User entered empty.	System	03 Mar 2021 21:56:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:52:24
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' answered with 'clarification: this medication was added as it was a prior medication stopped for short duration due to procedure, then restarted. It does not qualify as an AE as there was not worsening of medical history condition.' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:23:01
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:14:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 21:58:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Mar 2021 21:58:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Mar 2021 21:58:07
User entered 'Coumadin'	Marilyn Nguyen (b) (4)	03 Mar 2021 21:57:35
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Atrial flutter and ventricular septal defect'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '5'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '20 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered '20 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:57:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:57:35
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User entered empty.	System	03 Mar 2021 21:57:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User entered empty.	System	03 Mar 2021 21:57:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:11
User entered empty.	System	03 Mar 2021 21:57:35

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:25:52
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' answered with 'clarification: an AE is not indicated for worsening AF/VSD as there was not worsening of these medical conditions. Medication is primarily associated with AE#3' (Site from DM).	Paula Lins (b) (4) (b) (4)	30 Mar 2021 22:27:13
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:15:47
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[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) (b) (4)	04 Mar 2021 07:42:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:42:55
Data point term sent to Coder	System	03 Mar 2021 22:00:16
User entered 'Aspirin'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:59:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Atrial flutter, ventricular septal defect, acute left middle cerebral artery stroke'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '81'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:59:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '23 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	18 Mar 2021 22:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 22:12:41
	Roxanne Erolin (b) (4)	17 Mar 2021 19:29:16
User entered 'No (N)' reason for change: New Information	(b) (4)	17 Mar 2021 19:29:16
DataPoint Verified.	Roxanne Erolin (b) (4)	17 Mar 2021 19:29:16
	(b) (4)	04 Mar 2021 17:41:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 17:41:03
	Marilyn Nguyen (b) (4)	03 Mar 2021 21:59:13
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	18 Mar 2021 22:12:44
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 19:29:16
User entered '03 Mar 2021' reason for change: New Information	Roxanne Erolin (b) (4)	17 Mar 2021 19:29:16
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:59:13
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User entered 'I'	System	03 Mar 2021 21:59:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User entered '1'	System	03 Mar 2021 21:59:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:15
User entered '804 (804)'	System	03 Mar 2021 21:59:13

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, PRODUCTS YNOM: GAVILYTE C - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 11:07:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 11:07:33
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 COLON POLYPS should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:12:49
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening COLON POLYPS should be recorded, and update con med indication or provide clarification.' answered with 'clarification: this medication is associated with AE#2 Anemia Exacerbation.' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:29:33
Data point term sent to Coder	System	30 Mar 2021 22:28:42
Coding entries removed.	Paula Lins (b) (4)	30 Mar 2021 22:27:50

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE, PRODUCTSYNONYM: GAVILYTE C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 11:22:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 11:22:31
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 COLON POLYPS should be recorded, and update con med indication or provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 14:17:42
Data point term sent to Coder	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Polyethylene glycol-electrolytes (Gavilyte-C)'	System	03 Mar 2021 22:01:24
	Marilyn Nguyen (b) (4)	03 Mar 2021 22:00:36
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:36:05
User closed query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:12:13
Query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify. ' answered with 'Clarification: this medication was not used as therapeutic to treat Anemia Exacerbation but for diagnostic for source of Anemia Exacerbation' (Site from DM).	Paula Lins (b) (4)	30 Mar 2021 22:29:35
DataPoint Un-verified.	Paula Lins (b) (4)	30 Mar 2021 22:27:50
User entered 'ANEMIA EXACERBATION' reason for change: Data Entry Error	Paula Lins (b) (4)	30 Mar 2021 22:27:50
User opened query 'Per DM CLR: Please review and confirm if this medication was used to treat Anemia Exacerbation. Please update indication if applicable or please clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:00:46
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Colon polyps, anemia exacerbation'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:00:36

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '2000'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:00:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '17 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	04 Mar 2021 17:41:03
User entered '18 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:00:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 22:00:36
	Marilyn Nguyen (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User entered 'I'	System	03 Mar 2021 22:00:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User entered 'I'	System	03 Mar 2021 22:00:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:11:26
User entered '804 (804)'	System	03 Mar 2021 22:00:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 07:26:35
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' answered with 'Clarification: this does not qualify as an AE as there was no worsening of MH conditions. Medication was added as it was restarted after short duration discontinuation of chronic medication.' (Site from DM).	Paula Lins (b) (4) (b) (4)	30 Mar 2021 22:32:03
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 ATRIAL FLUTTER AND VENTRICULAR SEPTAL DEFECT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:18:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:05:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:05:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	03 Mar 2021 22:06:30
User entered 'Coumadin (Warfarin)'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'No (N)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Atrial flutter/Atrial fibrillation, ventricular septal defect'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 01:15:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 01:15:34
User entered '7.5 & 5.0' reason for change: Per Query Resolution	Lynn Gross (b) (4)	04 Mar 2021 01:15:34
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 22:05:33
User entered empty.	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Other (OTHER)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered '7.5mg - Monday, Wednesday, Friday 5.0mg - Tuesday, Thursday, Saturday, Sunday'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'once daily (QD)'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered 'Oral (ORAL)'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered '25 Feb 2021'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered '0'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 22:05:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 22:05:51
User entered 'Yes (Y)' reason for change: Per Query Resolution	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:51
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 22:05:33
User entered empty.	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:41:03
	Marilyn Nguyen (b) (4)	03 Mar 2021 22:05:33
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 22:05:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 11:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 11:36:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:03
Data point term sent to Coder	System	03 Mar 2021 22:11:35
User entered 'Omnipaque 350 (iohexol)'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:11:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Acute left middle cerebral artery stroke'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '80'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '21 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 22:11:33
	Marilyn Nguyen (b) (4)	
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:03
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4)	03 Mar 2021 22:11:33
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:41:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 17:41:03
	Marilyn Nguyen (b) (4)	03 Mar 2021 22:11:33
	(b) (4)	

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User entered empty.	System	03 Mar 2021 22:11:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User entered empty.	System	03 Mar 2021 22:11:33

US3582102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:17:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:10:19
User entered empty.	System	03 Mar 2021 22:11:33

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:17:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:38:48
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Yes (Y)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:50:50

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '15 Dec 2020'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:53:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Dental Bonding of 6 chipped teeth'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:53:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered 'Adverse Event (AE)'	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:53:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Paula Lins (b) (4) (b) (4)	29 Dec 2020 17:53:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered '29 Dec 2020'	(b) (4) Stephanie Pimienta (b) (4)	05 Jan 2021 21:56:36

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:18
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 22:22:09
DataPoint Un-verified.	Paula Lins (b) (4) (b) (4)	16 Mar 2021 21:03:02
Signature has been broken.	Paula Lins (b) (4) (b) (4)	16 Mar 2021 21:03:02
User entered 'CT OF HEAD (due to exacerbation of anemia)' reason for change: Data Entry Error	Paula Lins (b) (4) (b) (4)	16 Mar 2021 21:03:02
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered 'CT of head'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:56:36

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:18
User closed query 'Per DM CLR: Please note there is no Adverse Event that matches this reason for Concomitant Procedure/Surgery during this timeframe. Please review Procedure/Surgery performed and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:12:02
Query 'Per DM CLR: Please note there is no Adverse Event that matches this reason for Concomitant Procedure/Surgery during this timeframe. Please review Procedure/Surgery performed and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'Procedure was related to AE#2. updated for clarification.' (Site from DM).	Paula Lins (b) (4) (b) (4)	16 Mar 2021 21:03:26
User opened query 'Per DM CLR: Please note there is no Adverse Event that matches this reason for Concomitant Procedure/Surgery during this timeframe. Please review Procedure/Surgery performed and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 02:00:49
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	13 Feb 2021 00:00:17
User entered 'Adverse Event (AE)'	Stephanie Pimienta (b) (4)	05 Jan 2021 21:56:36

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:39:36
User signature succeeded.	Lisa Jackson (b) (4)	13 Feb 2021 00:00:17
User entered empty.	(b) (4) Stephanie Pimienta (b) (4)	05 Jan 2021 21:56:36

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:23
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '18 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:45:58

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:23
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Colonoscopy'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:45:58

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:23
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:45:58

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:23
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:45:58

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:27
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '18 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:29

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:27
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Upper endoscopy'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:29

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:27
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:29

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:27
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:29

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:31
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:46

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:31
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'EKG'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:46

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:31
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:46

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:31
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:46:46

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:34
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:04

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:34
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'CT Head without Contrast'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:04

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:34
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:04

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:34
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:04

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:38
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:38
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'CTA Head and Neck'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:38
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:38
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:43
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:24

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:43
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Chest X-ray'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:24

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:43
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:24

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:43
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:24

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:47
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered '21 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:48

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:47
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'MRI Brain without contrast'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:48

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:47
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:48

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:47
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:32
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	03 Mar 2021 21:48:48

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered '23 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:11

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'EKG'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:11

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:11

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:51
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:11

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:56
User closed query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #10. Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 04:46:38
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #10. Verify and update start/end dates or remove duplicate entry as necessary. ' answered with 'clarification: confirmation that 2 separate EKG's were performed 23FEB2021' (Site from DM).	Paula Lins (b) (4)	31 Mar 2021 20:59:43
User opened query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #10. Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:10:51
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered '23 Feb 2021'	Marilyn Nguyen (b) (4)	04 Mar 2021 22:50:28

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:56
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'EKG'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:28

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:56
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:28

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:15:56
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:28

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:17:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered '24 Feb 2021'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:17:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'CT Head without Contrast'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:17:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered 'Adverse Event (AE)'	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:56

US3582102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:17:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:01
User signature succeeded.	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:12:43
User entered empty.	Marilyn Nguyen (b) (4) (b) (4)	04 Mar 2021 22:50:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'USA-US124-2021-MRNA-1273-P301000002'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Lisa'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Jackson'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:36:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:34
User entered 'US'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:37:00
User entered '1'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'USA-US124-2021-MRNA-1273-P301000002'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Lisa'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Jackson'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:36:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:34
User entered 'US'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:37:00
User entered '1'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
User entered '25/Feb/2021 12:21'	(b) (4), (b) (6)	25 Feb 2021 12:21:17
	System	

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:36:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:34
User entered 'l'	(b) (4), (b) (6)	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'USA-US124-2021-MRNA-1273-P301000002'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Yes (Y)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'No (N)'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Lisa'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	04 Mar 2021 17:26:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 12:21:04
User entered 'Jackson'	System	25 Feb 2021 12:19:56

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:36:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:26:34
User entered 'US'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:37:00
User entered '1'	System	25 Feb 2021 12:21:17

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	18 Mar 2021 22:10:38
User entered '16/Mar/2021 13:36'	(b) (4), (b) (6)	16 Mar 2021 13:37:00
	System	

US3582102

Folder: SAE USA-US124-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:17:16

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.

Audit	User	Time (GMT)
User signature succeeded.	Lisa Jackson (b) (4)	01 Apr 2021 21:58:17
DataPoint Verified.	(b) (4)	18 Mar 2021 22:10:40
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 13:37:00