

US3512042 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:33:38

All time stamps listed in this document are displayed in GMT

US3512042

Form: Participant Creation

Generated On: 26 Nov 2020 09:33:38

[Participant ID](#)

US3512042

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

US3512042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	78
Age Units	YEARS
Age (Derived)	78
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1947
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1947
Start Year (derived)	1947
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

Condition	GASTRIC ULCER GASTRIC
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

Condition	LEFT SIDE OCULAR THROMBOSIS
Start date (dd MMM yyyy)	27 JUN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	27 JUN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

Condition	STROKE
Start date (dd MMM yyyy)	27 JUN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	27 JUN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

Condition	RIGHT HAND TREMOR
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

Condition	PELVIC REPAIR SURGERY
Start date (dd MMM yyyy)	08 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	08 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

Condition	BROKEN PELVIS SECONDARY TO FALL
Start date (dd MMM yyyy)	02 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	08 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:20
Height (<i>xxx.x</i>)	75.0 in
Weight (<i>xxx.x</i>)	177.0 lb
BMI (<i>xxx.x</i>)	22.16974 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 185331

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

Generated On: 26 Nov 2020 09:33:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:58
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 AUG 2020

What was the treatment time? (00:00-23:59) 13:28 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 13:28

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

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:58 (24 HR)
Collection date and time (derived)	12 AUG 2020 12:58

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:38

Collection date (<i>dd MMM yyyy</i>)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:40	12 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 14:05

PC Open Date & Time

12 AUG 2020 13:48

PC Close Date & Time

12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 12 AUG 2020 17:40

PC Open Date & Time 12 AUG 2020 17:13

PC Close Date & Time 13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:41

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

14 AUG 2020 12:25

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

16 AUG 2020 15:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

17 AUG 2020 17:13

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 7

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

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

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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

97.2 °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

18 AUG 2020 14:30

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 14:07

PC Open Date & Time

12 AUG 2020 13:48

PC Close Date & Time

12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 11:52

PC Open Date & Time

12 AUG 2020 17:13

PC Close Date & Time

13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 16:42

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:26

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:29

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 15:17

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 17:14

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 14:31

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 15:31
PC Open Date & Time	12 AUG 2020 13:48
PC Close Date & Time	12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 11:54
PC Open Date & Time	12 AUG 2020 17:13
PC Close Date & Time	13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	13 AUG 2020 16:43
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	14 AUG 2020 12:27
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	15 AUG 2020 12:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	16 AUG 2020 15:17
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	17 AUG 2020 17:15
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

Yes ☐	
PC Time stamp	18 AUG 2020 14:31
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

Was Contact Attempted?

Yes ☒

No ☐

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

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512042

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:33:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3512042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

AEID	USA-US065-2020-MRNA-1273-P30 1000001
Adverse event	CARDIOPULMONARY ARREST
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	1 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

		PT EXPERIENCED FATAL SAE ON 9/1/2020. HE STOPPED ASA 2-5 DAYS PRIOR TO DEATH IN PREPARATION FOR PLANNED COCHLEAR IMPLANT PROCEDURE ON 9/3/2020. PT HAS HISTORY OF A-FIB, HTN AND HYPERLIPIDEMIA. HE WAS NEGATIVE FOR FEVER, WEIGHT CHANGE, SWELLING. HIS WIFE REPORTED HE WAS SICK ON SUNDAY AND HAD THREE EPISODES OF VOMITING ON 8/31/2020
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)		

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

AEID	
Adverse event	VOMITTING X3
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	31 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

AEID	
Adverse event	MALAISE
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)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:38

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

Yes ☒

No ☐

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	ENTERIC ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	POST 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 ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS HIP
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	LIPITOR
Prophylaxis	Yes ☐ No ☒
Indication	HIGH CHOLESTEROL
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	COZAAR
Prophylaxis	Yes ☐ No ☒
Indication	HIGH BLOOD PRESSURE
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 ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HIGH BLOOD PRESSURE
Dose per administration	12.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	HYDROCODONE
Prophylaxis	Yes ☐ No ☒
Indication	HIP PAIN
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 ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	MIRTAZAPINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	15
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

Name of Medication	FLOMAX
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

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

US3512042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:33:38

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3512042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:38

Date of dosing discontinuation (dd MMM yyyy)

01 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☒

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

Date of study discontinuation/completion (dd MMM yyyy) 1 SEP 2020

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) 1 SEP 2020

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

SAEID	USA-US065-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:38

SAEID	USA-US065-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/SEP/2020 14:18
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

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:38

SAEID	USA-US065-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/SEP/2020 19:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:38

SAEID	USA-US065-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/SEP/2020 17:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3512042 (Prod: Jacksonville Center for Clinical Research Center)

US3512042

Form: Participant Creation

Generated On: 26 Nov 2020 09:33:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3512042'	RWS_ENDPOINT ENDPOINT (b) (4) 	12 Aug 2020 16:34:40

US3512042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:34:41

US3512042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:34:42

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '78'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '78'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered 'Male (M)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '1'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:38

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered '12 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'Amendment 2 (2)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:34:41

US3512042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:42:53
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:00
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:56:51

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:58:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:58:22
Data point term sent to Coder	System	12 Aug 2020 21:57:21
User entered 'allergy to sulfa'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2005'	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:59:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:59:12
Data point term sent to Coder	System	12 Aug 2020 21:58:22
User entered 'allergy to penicillin'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 21:57:36
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2005'	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 22:00:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Aug 2020 22:00:20
Data point term sent to Coder	System	12 Aug 2020 21:59:24
User entered 'environmental allergies'	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:32:01
User entered 'un UNK 2000' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 11:32:01
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	
User entered empty.	System	12 Aug 2020 21:58:47
	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Aug 2020 11:32:01
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Aug 2020 11:32:01
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
Data point term sent to Coder	System	12 Aug 2020 21:59:24
User entered 'seasonal allergies'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1947'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1947'	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1947'	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:01:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:01:23
Data point term sent to Coder	System	12 Aug 2020 22:00:25
User entered 'gastroesophageal reflux disease'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1998'	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:02:24
Data point term sent to Coder	System	12 Aug 2020 22:01:26
User entered 'heartburn'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:00:29
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1998'	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:19:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:19:24
Data point term sent to Coder	System	13 Aug 2020 11:32:40
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:32:33
User entered 'gastric ULCER gastric' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:32:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Ulcers NEC, PT: Ulcer, LLT: Ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:03:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:03:09
Data point term sent to Coder	System	12 Aug 2020 22:02:27
User entered 'Ulcer'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4)	12 Aug 2020 22:01:44
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:05:10
Data point term sent to Coder	System	12 Aug 2020 22:04:28
User entered 'constipation'	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:03:36
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:05:10
Data point term sent to Coder	System	12 Aug 2020 22:04:28
User entered 'enlarged prostate'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un Nov 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:06:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:06:10
Data point term sent to Coder	System	12 Aug 2020 22:05:29
User entered 'erectile dysfunction'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:04:58
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:14:22
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:54:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:54:45
Data point term sent to Coder	System	20 Oct 2020 20:53:39
Query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:53:32
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:53:26
User entered 'BILATERAL CATARACTS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:53:26
User opened query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:17:21
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:07:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:07:26
Data point term sent to Coder	System	12 Aug 2020 22:06:30

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
User entered 'cataracts'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2000'	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2000'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Intraocular lens implant, LLT: Lens implant - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:21:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:21:22
Data point term sent to Coder	System	12 Aug 2020 22:09:35
User entered 'bilateral lens implant'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:08:45

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:08:45

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:54:05
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:56:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:56:38
Data point term sent to Coder	System	20 Oct 2020 20:54:41
Query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'BILATERAL' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:54:03
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:53:58
User entered 'BILATERAL HEARING LOSS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:53:58
User opened query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:17:38
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:10:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:10:13
Data point term sent to Coder	System	12 Aug 2020 22:09:34

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
User entered 'hearing loss'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:09:14
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinal bleeding and vascular disorders (excl retinopathy), PT: Retinal vascular thrombosis, LLT: Retinal vascular thrombosis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:23:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:23:01
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	22 Oct 2020 08:06:22
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	20 Oct 2020 20:54:51
' answered with 'PREDOMINATELY LEFT SIDED' (Site from DM).		
Data point term sent to Coder	System	20 Oct 2020 20:54:41
User entered 'LEFT SIDE OCULAR THROMBOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:54:39
User opened query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	23 Sep 2020 12:17:51
' (Site from DM).		
Data point term sent to Coder	System	12 Aug 2020 22:10:37
User entered 'ocular thrombosis'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jun 2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jun 2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
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: Stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:12:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:12:14
Data point term sent to Coder	System	12 Aug 2020 22:11:43
User entered 'stroke'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4)	12 Aug 2020 22:11:23
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4)	12 Aug 2020 22:11:23
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jun 2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jun 2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:43:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:43:22
Data point term sent to Coder	System	12 Aug 2020 22:12:46
User entered 'right hand tremor'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1990'	Brenda Anderson (b) (4)	12 Aug 2020 22:12:11
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:12:11
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '1990'	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:14:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:14:16
Data point term sent to Coder	System	12 Aug 2020 22:13:48
User entered 'sleep apnea'	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2012'	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 11:34:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 11:34:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 11:34:41
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:13:21
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2012'	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:28:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:28:21
Data point term sent to Coder	System	12 Aug 2020 22:14:51
User entered 'fracture left hip'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:02
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:02
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:16:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:16:15
Data point term sent to Coder	System	12 Aug 2020 22:14:52
User entered 'high cholesterol'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:14:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:14:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:14:29
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:14:23
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2005'	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:17
Data point term sent to Coder	System	12 Aug 2020 22:16:55
User entered 'high blood pressure'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:36:36
User entered 'un UNK 2005' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 11:36:36
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	
User entered empty.	System	12 Aug 2020 22:15:56
	Brenda Anderson (b) (4)	12 Aug 2020 22:15:56
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	13 Aug 2020 11:36:36
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 11:36:36
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:05:21
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'NO MED REPORTED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:55:31
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:18:19
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:16
Data point term sent to Coder	System	12 Aug 2020 22:16:56
User entered 'paroxysmal atrial fibrillation'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2015'	Brenda Anderson (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:16:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:16:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:16:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:16:52
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:16:52
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2015'	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:20:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:20:16
Data point term sent to Coder	System	12 Aug 2020 22:18:58
User entered 'anxiety'	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44
	(b) (4)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44
	(b) (4)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:18:44
	(b) (4)	

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:21:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:21:16
Data point term sent to Coder	System	12 Aug 2020 22:20:00
User entered 'depression'	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:22:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:22:17
Data point term sent to Coder	System	12 Aug 2020 22:21:01
User entered 'insomnia'	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59
	(b) (4)	

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:41:28
User entered 'un UNK 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	13 Aug 2020 11:41:28
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	
User entered empty.	System	12 Aug 2020 22:20:59
	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59
	(b) (4)	

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59
	(b) (4)	

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	13 Aug 2020 11:41:28
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 11:41:28
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Acetabulum fracture, LLT: Acetabulum fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:39:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:39:16
Data point term sent to Coder	System	12 Aug 2020 22:22:02
User entered 'acetabular fracture'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

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Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Nov 2019' reason for change:	Brenda Anderson (b) (4)	12 Aug 2020 22:25:32
Data Entry Error	(b) (4)	
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:21:50
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:25:32
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Aug 2020 22:25:32
User entered 'Jan 2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	12 Aug 2020 22:25:32
User entered 'Jan 2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Acetabular surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
Data point term sent to Coder	System	12 Aug 2020 22:27:13
User entered 'acetabular surgery'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un Nov 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:10
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:06:00
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'PATIENT HAD TWO SURGERIES, WILL ADD SECOND ON SEPERATE LOG LINE' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:56:39
User entered 'UN Nov 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:56:19
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:18:56
User entered 'un Dec 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	20 Oct 2020 20:56:19
User entered 'Dec 2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:29:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 22:29:20
Data point term sent to Coder	System	12 Aug 2020 22:28:16
User entered 'spinal stenosis'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2013'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2013'	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:11:20
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:57:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Pelvic operation, LLT: Pelvic operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:33:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:33:51
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:19:32
Data point term sent to Coder	System	12 Aug 2020 22:29:19
User entered 'pelvic repair surgery'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '08 Aug 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08
	(b) (4)	

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Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	12 Aug 2020 22:30:14
User entered '08 Aug 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:30:14
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	12 Aug 2020 22:29:08
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	12 Aug 2020 22:30:14
User entered 'Jan 2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis chronic, LLT: Chronic cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:35:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:35:19
Data point term sent to Coder	System	13 Aug 2020 11:34:40
User entered 'chronic cholecystitis'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	13 Aug 2020 11:33:46

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Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:04:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:03:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:03:31
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'EXACT LOCATIONS UNKNOWN' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:59:57
Data point term sent to Coder	System	20 Oct 2020 20:59:51
User entered 'GENERALIZED UNSPECIFIED JOINT OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:59:45
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:59:23
User entered 'GENERALIZED MULTIPLE JOINT OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:59:23
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:19:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:37:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:37:29

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	13 Aug 2020 11:36:41
User entered 'osteoarthritis'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10

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Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10

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Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10

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Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 09:52:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 09:52:16
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
Data point term sent to Coder	System	20 Oct 2020 20:58:48
User entered 'BROKEN PELVIS SECONDARY TO FALL'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '02 Aug 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '08 Aug 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Acetabular surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:59:44
Data point term sent to Coder	System	20 Oct 2020 20:58:50
User entered 'ACETABULAR SURGERY'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '12:20'	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
	(b) (4)	

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:20'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '75.0' in	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '177.0' lb	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '22.16974'	System	16 Sep 2020 23:53:43
User entered '22.2'	System	12 Aug 2020 22:35:52
DataPoint set to visible.	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Aug 2020 22:35:52
DataPoint set to visible.	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 16:48:38
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:35:58
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Aug 2020 22:35:52
User entered empty.	System	12 Aug 2020 22:35:52
	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
	(b) (4)	

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:49
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Aug 2020 22:36:10

US3512042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:51:49
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	12 Aug 2020 22:36:10

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:36:02
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:42:37
Query 'Data is required. Please complete.' answered with 'done' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:38:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:37:57
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '1'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:38

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:44

US3512042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:44

US3512042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:44

US3512042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 19:20:44

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:44:38

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:54:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:54:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:44:38
User entered '185331' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:44:38

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:44:38

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:56
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:56

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:56

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:55:56
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:33:09
User entered 'No (N)'	(b) (4)	04 Nov 2020 16:33:04
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:48:56
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:47:55

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12:20'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:20'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '98.1' F	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered empty.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '54'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '142'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:27:27
User closed query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:27:23
Query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' answered with 'corrected' (Site from CRA).	Brenda Anderson (b) (4)	06 Nov 2020 18:58:02
User entered '92' reason for change: Data Entry Error	Brenda Anderson (b) (4)	06 Nov 2020 18:57:50
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:20
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User opened query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 12:55:53
User entered '82'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:38

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '13:58'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:58'	System	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 06:23:47
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per sub investigator' (Site from System).	Brenda Anderson (b) (4) (b) (4)	21 Sep 2020 19:37:51
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:53:43
User entered '96.7' F	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered empty.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '53'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '150'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User closed query 'Per CDM: Please confirm the value for Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:19:49
Query 'Per CDM: Please confirm the value for Diastolic BP.' answered with 'changed per source' (Site from DM).	Brenda Anderson (b) (4)	10 Sep 2020 18:01:20
User entered '74' reason for change: Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 18:01:09
User opened query 'Per CDM: Please confirm the value for Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 13:05:41
User entered '14'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:24
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:46

US3512042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:24
User entered empty.	Brenda Anderson (b) (4)	28 Aug 2020 19:22:46

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:41:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered '12 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered '13:28'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:28'	System	12 Aug 2020 17:41:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'Left Arm (LEFT ARM)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'ONCE'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered '12:58'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:01
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:58'	System	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered '12:40'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:40'	System	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered empty.	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:59:17
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:24:43

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:24:43

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:24', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187'	System	12 Aug 2020 18:05:08
User entered 'Yes (Y)'	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187'	System	12 Aug 2020 18:05:08
User entered '96.7'	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187'	System	12 Aug 2020 18:05:08
User entered 'No (N)'	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:05:04', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187'	System	12 Aug 2020 18:05:08
User entered '12 Aug 2020 14:05'	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:12', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d'	System	12 Aug 2020 21:41:07
User entered 'Yes (Y)'	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d' User entered '97.3'	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d'	System	12 Aug 2020 21:41:07
User entered 'No (N)'	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d'	System	12 Aug 2020 21:41:07
User entered '12 Aug 2020 17:40'	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951'	System	13 Aug 2020 20:41:50
User entered 'Yes (Y)'	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951'	System	13 Aug 2020 20:41:50
User entered '98.1'	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951'	System	13 Aug 2020 20:41:50
User entered 'No (N)'	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:43', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951'	System	13 Aug 2020 20:41:50
User entered '13 Aug 2020 16:41'	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:24:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa'	System	14 Aug 2020 16:25:18
User entered 'Yes (Y)'	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:02', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa' User entered '97.2'	System	14 Aug 2020 16:25:18
	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa'	System	14 Aug 2020 16:25:18
User entered 'No (N)'	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:16', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa' User entered '14 Aug 2020 12:25'	System	14 Aug 2020 16:25:18
	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:25', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered 'Yes (Y)'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered '96.7'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered 'No (N)'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered '15 Aug 2020 12:28'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:17', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2'	System	16 Aug 2020 19:16:40
User entered 'Yes (Y)'	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:23', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2'	System	16 Aug 2020 19:16:40
User entered '96.3'	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2'	System	16 Aug 2020 19:16:40
User entered 'No (N)'	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2'	System	16 Aug 2020 19:16:40
User entered '16 Aug 2020 15:16'	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0'	System	17 Aug 2020 21:13:39
User entered 'Yes (Y)'	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0' User entered '97.4'	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0'	System	17 Aug 2020 21:13:39
User entered 'No (N)'	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0'	System	17 Aug 2020 21:13:39
User entered '17 Aug 2020 17:13'	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e'	System	18 Aug 2020 18:30:36
User entered 'Yes (Y)'	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e' User entered '97.2'	System	18 Aug 2020 18:30:36
	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:28', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e'	System	18 Aug 2020 18:30:36
User entered 'No (N)'	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:35', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e'	System	18 Aug 2020 18:30:36
User entered '18 Aug 2020 14:30'	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:08', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'None (1)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:24', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'No (N)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:32', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'No (N)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'None (1)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:07:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered '12 Aug 2020 14:07'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'No (N)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:57', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'No (N)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'None (1)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:28', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered '13 Aug 2020 11:52'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:59', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered 'No (N)'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered 'No (N)'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered 'None (1)'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:41', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered '13 Aug 2020 16:42'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd'	System	14 Aug 2020 16:26:37
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:14', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd'	System	14 Aug 2020 16:26:37
User entered 'No (N)'	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd'	System	14 Aug 2020 16:26:37
User entered 'No (N)'	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:25', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd'	System	14 Aug 2020 16:26:37
User entered 'None (1)'	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered '14 Aug 2020 12:26'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'None (1)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'No (N)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'No (N)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'None (1)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered '15 Aug 2020 12:29'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'None (1)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'No (N)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:58', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'No (N)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:04', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'None (1)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered '16 Aug 2020 15:17'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:47', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'None (1)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:56', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'No (N)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:02', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'No (N)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:08', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'None (1)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered '17 Aug 2020 17:14'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140'	System	18 Aug 2020 18:31:09
User entered 'None (1)'	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140'	System	18 Aug 2020 18:31:09
User entered 'No (N)'	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:53', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140'	System	18 Aug 2020 18:31:09
User entered 'No (N)'	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140'	System	18 Aug 2020 18:31:09
User entered 'None (1)'	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140'	System	18 Aug 2020 18:31:09
User entered '18 Aug 2020 14:31'	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:29:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc'	System	12 Aug 2020 19:31:18
User entered 'No interference with activity (1)'	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:07', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:13', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc'	System	12 Aug 2020 19:31:18
User entered 'None (0)'	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:17', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc'	System	12 Aug 2020 19:31:18
User entered 'None (0)'	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc'	System	12 Aug 2020 19:31:18
User entered 'No (N)'	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:31:12', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc'	System	12 Aug 2020 19:31:18
User entered '12 Aug 2020 15:31'	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'No interference with activity (1)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'Some interference with activity (2)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:22', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'None (0)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'None (0)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:34', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'None (0)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'None (0)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:48', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'No (N)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:54:01', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered '13 Aug 2020 11:54'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:01', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'None (0)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:09', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'None (0)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:22', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'None (0)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'None (0)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:35', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'None (0)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'No (N)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:55', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered '13 Aug 2020 16:43'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'None (0)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'No interference with activity (1)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:57', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'None (0)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'None (0)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:07', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'None (0)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'None (0)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered 'No (N)'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:29', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6'	System	14 Aug 2020 16:27:31
User entered '14 Aug 2020 12:27'	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'None (0)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:51', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'No interference with activity (1)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:55', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'None (0)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:59', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'None (0)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'None (0)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:09', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'None (0)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered 'No (N)'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619'	System	15 Aug 2020 16:30:32
User entered '15 Aug 2020 12:30'	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:33', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:39', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'None (0)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:48', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered 'No (N)'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:56', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered '16 Aug 2020 15:17'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:29', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:34', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:39', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:41', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'None (0)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:58', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'No (N)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:15:10', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered '17 Aug 2020 17:15'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:13', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:16', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:20', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:23', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'None (0)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered 'No (N)'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21'	System	18 Aug 2020 18:32:00
User entered '18 Aug 2020 14:31'	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered '19 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered empty.	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:04:39
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:19

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:25:19

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered '26 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:07:01
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:25

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:37:25

US3512042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:19
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Sep 2020 12:31:09

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:17:49
User entered 'USA-US065-2020-mRNA-1273-P301000001'	System	02 Sep 2020 18:17:12
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 18:17:12

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:32
Query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' answered with 'Cause of death on death certificate from patient PCP is cardiopulmonary arrest. Patient passed away at home, there are no additional details or diagnosis' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:43:31
User opened query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:04:10
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:12:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 14:12:51
Data point term sent to Coder	System	02 Sep 2020 14:08:51
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:42
Query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' answered with 'will update AE page to include symptoms reported by patient family. He had 3 episodes of vomiting in the days leading up to his passing.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:54:00
User opened query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:05
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 14:10:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 14:10:32
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	02 Sep 2020 14:10:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 14:10:11
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 14:10:11
User entered 'un:un' (non-conformant).	Brenda Anderson (b) (4)	02 Sep 2020 14:10:11
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 14:10:32
User entered '1 Sep 2020 UN:UN' (non-conformant).	System	02 Sep 2020 14:10:11
User entered empty.	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1 Sep 2020'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV query: Please update the severity to grade 5 as the subject died.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:53
Query 'PV query: Please update the severity to grade 5 as the subject died.' answered with 'grade 5 is not an option on the radio buttons provided?' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:50:55
User opened query 'PV query: Please update the severity to grade 5 as the subject died.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:06:56
User entered 'Grade 4 (Grade 4)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:01:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:01:28
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Brenda Anderson (b) (4)	02 Sep 2020 20:01:28
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:08:28
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'None (NONE)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Fatal (FATAL)'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:34
User closed query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:29
User closed query 'PV Query: What type of CVA did the subect had in 2016 (hemorrhagic, ischemic)?' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:23
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:20
Query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' answered with 'will email' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:50:30
Query 'PV Query: What type of CVA did the subect had in 2016 (hemorrhagic, ischemic)?' answered with '"ocular thrombus stroke" is what patient reported at time of med history collection, "status post CVA" and "stroke" are all that is listed in medical records' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:48:40
Query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' answered with 'unknown, none of those symptoms were reported by family members and none reported in weekly protocol phone calls.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:44:52
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'No known autopsy available' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:44:15
User opened query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:10:16
Query 'PV query: Please provide death certificate.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:10:04

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:07:17
User opened query 'PV query: Please provide death certificate.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:48
User opened query 'PV Query: What type of CVA did the subect had in 2016 (hemorrhagic, ischemic)?' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:32
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:02:36
User entered 'PT EXPERIENCED FATAL SAE ON 9/1/2020. HE STOPPED ASA 2-5 DAYS PRIOR TO DEATH IN PREPARATION FOR PLANNED COCHLEAR IMPLANT PROCEDURE ON 9/3/2020. PT HAS HISTORY OF A-FIB, HTN AND HYPERLIPIDEMIA. HE WAS NEGATIVE FOR FEVER, WEIGHT CHANGE, SWELLING. HIS WIFE REPORTED HE WAS SICK ON SUNDAY AND HAD THREE EPISODES OF VOMITING ON 8/31/2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	02 Sep 2020 14:08:55
User entered 'pt experienced fatal SAE on 9/1/2020. He stopped ASA 2-5 days prior to death in preparation for planned cochlear implant procedure on 9/3/2020. Pt has history of a-fib, htn and hyperlipidemia. HE was neegative for fever, weight change, swelling. HIs wife reported he was sick on Sunday and had three episodes of vomiting on 8/31/2020'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:49:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:49:42
Data point term sent to Coder	System	18 Sep 2020 21:10:07
User entered 'VOMITTING X3' reason for change:	Brenda Anderson (b) (4)	18 Sep 2020 21:09:11
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 20:44:22
User entered 'vommitting x3'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '31 Aug 2020'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '31 Aug 2020'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 20:44:59
User entered '1' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 20:44:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	18 Sep 2020 20:44:00
User entered '0'	System	18 Sep 2020 20:44:00
	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:59
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:15:46
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'pt passed no illness visit completed' (Site from DM).	Brenda Anderson (b) (4)	23 Oct 2020 14:55:27
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:36:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Malaise, LLT: Malaise - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:05:42
Data point term sent to Coder	System	18 Sep 2020 21:04:57
User entered 'malaise'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '30 Aug 2020'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '01 Sep 2020'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:05:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:05:12
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 21:05:12
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:50
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:05:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:05:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:05:12
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:50
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:16:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'pt passed no illness visit completed' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	23 Oct 2020 14:55:39
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:36:46
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
Data point term sent to Coder	System	18 Sep 2020 21:11:09
User entered 'Nausea'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '30 Aug 2020'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '01 Sep 2020'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:10:27
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 21:10:27
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:17
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:10:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:27
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:17
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17
	(b) (4)	

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:33:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 21:10:17

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:53
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:44:16

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
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: ENTERIC ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 00:17:19
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 Aug 2020 00:17:19
Data point term sent to Coder	System	12 Aug 2020 22:49:50
User entered 'enteric aspirin'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	23 Oct 2020 14:56:25
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:38:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	23 Oct 2020 14:56:32
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:39:01
User entered 'Post stroke'	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '81'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:36:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:49:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:49:18
User entered 'un UNK 2016'	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:52:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:52:15
Data point term sent to Coder	System	12 Aug 2020 22:50:52
User entered 'tylenol'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS HIP (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:37
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS HIP (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:39:23
User entered 'osteoarthritis hip'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '600'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:52:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:50:48
User entered 'un UNK 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 22:55:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 22:55:20
Data point term sent to Coder	System	12 Aug 2020 22:53:58
User entered 'benadryl'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'seasonal allergies'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '25'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:53:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:53:21
User entered 'un UNK 2000'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
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) (b) (4)	12 Aug 2020 22:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:33
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:57:01 12 Aug 2020 22:56:52
User entered 'lipitor' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:56:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:56:18
Data point term sent to Coder User entered 'atorvastatin'	System Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:59 12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high cholesterol'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '20'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:54:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:54:32
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
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) (b) (4)	12 Aug 2020 22:57:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:20
Data point term sent to Coder User entered 'Cozaar'	System Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:57:01 12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high blood pressure'	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '100'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is ' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:56:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:56:25
User entered 'un UNK 2005'	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:06:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:06:28
Data point term sent to Coder	System	12 Aug 2020 22:59:04
User entered 'hydrochlorothiazide'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high blood pressure'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '12.5'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:59:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:58:18
User entered 'un UNK 2015'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:03:31
Data point term sent to Coder	System	12 Aug 2020 23:00:08
User entered 'hydrocodone'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:50
Query 'Per DM CLR: Please update the indication to reflect the location of HIP PAIN (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:48
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:40:58
User opened query 'Per DM CLR: Please update the indication to reflect the location of HIP PAIN (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:40:46
User entered 'hip pain'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '5'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:59:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:59:49
User entered 'un Dec 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:52:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:52:53
Data point term sent to Coder	System	02 Sep 2020 12:51:21
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 12:50:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 10:43:04
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 Aug 2020 10:43:04
Data point term sent to Coder	System	14 Aug 2020 20:37:52
User closed query '	System	14 Aug 2020 20:37:50
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Query '	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 20:37:50
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' answered with 'data updated' (Site from System).		
Data point term sent to Coder	System	14 Aug 2020 20:37:50
User entered 'mirtazapine' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 20:37:43
User opened query '	Coder Import (b) (4) (b) (4)	13 Aug 2020 06:57:16
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Data point term sent to Coder	System	12 Aug 2020 23:02:14

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Acudep'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'depression' reason for change: Data Entry Error	Brenda Anderson (b) (4)	02 Sep 2020 12:50:50
User entered 'benign prostatic hyperplasia'	Brenda Anderson (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '15'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 23:02:11
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 23:02:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 23:02:11
User entered 'un Nov 2019'	Brenda Anderson (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
Data point term sent to Coder	System	12 Aug 2020 23:04:16
User entered 'Flomax'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'benign prostatic hyperplasia'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0.4'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4)	12 Aug 2020 23:04:04
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	12 Aug 2020 23:04:04
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 23:04:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 23:04:04
User entered 'un Nov 2019'	Brenda Anderson (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:33:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 23:04:04

US3512042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:38

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 11:29:11
Query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4)	10 Sep 2020 17:57:37
User entered '01 Sep 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:57:28
User opened query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:33:08
User entered '12 Aug 2020'	Brenda Anderson (b) (4)	02 Sep 2020 14:56:39

US3512042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 11:29:30
Query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4)	10 Sep 2020 17:57:47
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:57:28
User opened query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:25:24
User entered 'SAE (specify) (SAE)'	Brenda Anderson (b) (4)	02 Sep 2020 14:56:39

US3512042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:57:54
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:57:54
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:57:28
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4)	02 Sep 2020 14:56:39

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	10 Sep 2020 17:48:19
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:48:19
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	(b) (4)	02 Sep 2020 14:58:24
User entered 'SAE (specify) (SAE)'	Brenda Anderson (b) (4)	02 Sep 2020 14:58:24
	(b) (4)	

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:48:32
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:48:32
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:48:19
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:24:08
Query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' answered with 'AE#1' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 12:05:22
User opened query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:18:51
Query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:38:16
User opened query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:49:45
User closed query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	10 Sep 2020 17:59:54
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:59:54
User opened query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	10 Sep 2020 17:48:19
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:38

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered 'Unknown (UNK)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered 'US' (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered 'US' (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '02/Sep/2020 14:18'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered 'US' (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '02/Sep/2020 19:51'	System	02 Sep 2020 23:51:40

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 23:51:40

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered 'US' (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '20/Sep/2020 17:17'	System	20 Sep 2020 21:17:57

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 21:17:57