

US3022276 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:51:30

All time stamps listed in this document are displayed in GMT

US3022276

Form: Participant Creation

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

[Participant ID](#)

US3022276

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

US3022276

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	PUERTO RICAN
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Feb 2021 00:33:59

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Feb 2021 00:33:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Feb 2021 00:33:59

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	PARTIAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	VITAMIN B-12 DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	ALLERGIC CONJUNCTIVITIS
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	OVARIAN CYSTS - BILATERAL BENIGN
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Condition	BACK INJURY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:55
Height (xxx.x)	162 cm
Weight (xxx.x)	91.2 kg
BMI (xxx.x)	34.75080 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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: Childbearing Potential

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Date of assessment (dd MMM yyyy) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2004

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

DISABLED VETERAN,
SHOPPING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:33:59

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144679

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	16:47 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:47
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 16:16 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 16:16

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

15:14 (24 HR)

Collection date and time (derived)

21 AUG 2020 15:14

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:45	21 AUG 2020 14:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 16:48

PC Open Date & Time

21 AUG 2020 16:36

PC Close Date & Time

21 AUG 2020 19:06

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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 99.4 °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	21 AUG 2020 20:15
PC Open Date & Time	21 AUG 2020 20:01
PC Close Date & Time	22 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

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

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

22 AUG 2020 12:10

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

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

99.4 °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

23 AUG 2020 12:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

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

93.1 °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

24 AUG 2020 12:04

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

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

96.1 °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

25 AUG 2020 13:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 18:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

27 AUG 2020 17:25

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 16:48

PC Open Date & Time

21 AUG 2020 16:36

PC Close Date & Time

21 AUG 2020 19:06

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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

21 AUG 2020 20:15

PC Open Date & Time

21 AUG 2020 20:01

PC Close Date & Time

22 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

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

22 AUG 2020 12:11

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

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

23 AUG 2020 12:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

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

24 AUG 2020 12:04

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

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

25 AUG 2020 13:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

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

26 AUG 2020 18:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

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

27 AUG 2020 17:25

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

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 ☐

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 16:49
PC Open Date & Time	21 AUG 2020 16:36
PC Close Date & Time	21 AUG 2020 19:06

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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 ☐

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 20:16
PC Open Date & Time	21 AUG 2020 20:01
PC Close Date & Time	22 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:11
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 13:50
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:33
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

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 ☒

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 17:26
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3022276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:34
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:18
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3022276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 10:46

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

US3022276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

24 SEP 2020 09:55

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:06	24 SEP 2020 10:06
Nasopharyngeal Swab 2	No		

US3022276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

24 SEP 2020 11:20

PC Open Date & Time

24 SEP 2020 11:06

PC Close Date & Time

24 SEP 2020 13:36

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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 99.1 °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	24 SEP 2020 14:38
PC Open Date & Time	24 SEP 2020 14:31
PC Close Date & Time	25 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	25 SEP 2020 12:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

26 SEP 2020 13:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 14:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:53

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

29 SEP 2020 20:29

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:09

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 11:20

PC Open Date & Time

24 SEP 2020 11:06

PC Close Date & Time

24 SEP 2020 13:36

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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

24 SEP 2020 14:38

PC Open Date & Time

24 SEP 2020 14:31

PC Close Date & Time

25 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

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

25 SEP 2020 12:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

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

26 SEP 2020 13:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

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

27 SEP 2020 14:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

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

28 SEP 2020 13:53

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

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

29 SEP 2020 20:29

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

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

30 SEP 2020 18:09

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

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 ☐

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:20
PC Open Date & Time	24 SEP 2020 11:06
PC Close Date & Time	24 SEP 2020 13:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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 ☐

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 14:39
PC Open Date & Time	24 SEP 2020 14:31
PC Close Date & Time	25 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

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 ☒

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:58
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2436

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:41
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 13:53
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

115 of 2436

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 20:29
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

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 ☒

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EAB) (1725)

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:10
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 01 OCT 2020 22:19

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 22:19
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3022276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:34:26

Generated On: 09 Jun 2021 14:51:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:34:26

Generated On: 09 Jun 2021 14:51:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:35
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:34:26

Generated On: 09 Jun 2021 14:51:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3022276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:34:26

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

10:44 (24 HR)

Collection date and time (derived)

23 OCT 2020 10:44

US3022276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:34:00

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 16:44:23
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 08:28:53

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 05:18:11

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 04:43:01

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 07:31:56
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 05:12:50

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 08:04:24

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 13:06:16

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 13:08:15

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 10:47:50

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 13:56:11

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 04:57:47

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:08:03
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 19:01:55

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 04:07:37

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 12:09:35

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 13:12:29

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 03:59:27

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 09:04:18

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 05:57:27

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 MAR 2021 17:04:08
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 10:12:25

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 11:19:29

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 10:33:49

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 04:24:06

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:39:37

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 04:05:32

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 04:09:55

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Patient Cloud Open Date & Time	22 AUG 2021 00:01
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Patient Cloud Close Date & Time	26 AUG 2021 23:59
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US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Patient Cloud Open Date & Time	12 SEP 2021 00:01
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Patient Cloud Close Date & Time	16 SEP 2021 23:59
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US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Patient Cloud Open Date & Time	26 SEP 2021 00:01
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Patient Cloud Close Date & Time	30 SEP 2021 23:59
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US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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10 MAR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Patient Cloud Open Date & Time	17 JUL 2022 00:01
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Patient Cloud Close Date & Time	21 JUL 2022 23:59
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US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 754

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

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

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

US3022276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:51:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 09:04:08

US3022276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:10:10

Generated On: 09 Jun 2021 14:51:30

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

Visit date (dd MMM yyyy)	09 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:23:26

Generated On: 09 Jun 2021 14:51:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3022276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:10:10

Generated On: 09 Jun 2021 14:51:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:10:10

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

14:42 (24 HR)

Collection date and time (derived)

09 MAR 2021 14:42

US3022276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:10:10

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:20:49

Generated On: 09 Jun 2021 14:51:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022276

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:20:48

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022276

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022276

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:30

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

US3022276

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:51:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022276

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

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

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

Visit date (dd MMM yyyy)	01 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3022276

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:23:26

Generated On: 09 Jun 2021 14:51:30

Date of updated informed consent (dd MMM yyyy) 01 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 01 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3022276

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 FEB 2021

Collection time (00:00-23:59)

10:34 (24 HR)

Collection date and time (derived)

01 FEB 2021 10:34

US3022276

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 FEB 2021

Collection time (00:00 - 23:59)

10:59

Collection Date and Time (derived)

01 FEB 2021 10:59

US3022276

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

AEID	USA-US051-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING OF BACK INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
SUBJECT WENT TO THE HOSPITAL FOR A PRE-PLANNED SURGERY	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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EAB) (1725)

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US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 23:02:19

Generated On: 09 Jun 2021 14:51:30

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

Yes ☒

No ☐

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

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication EMPAGLIFLOZIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication NORETHINPROLE

Prophylaxis Yes ☐
No ☒

Indication ENDOMETRIOSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication VARENICLINE

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication OLOPATADINE HCL

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC CONJUNCTIVITIS

Dose per administration 0.1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify DROP

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 4.5

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1992	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication CYANOCOBALAMIN

Prophylaxis Yes ☐
No ☒

Indication VITAMIN B-12 DEFICIENCY

Dose per administration 1000

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☒
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ASPART INSULIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 100

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31	AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ESTRADIOL PATCH

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT

Dose per administration 0.05

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

TWICE A WEEK

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication MONTELKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2003
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 8

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1988	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES & PAIN AT
INJECTION SITE

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU VACCINE

Dose per administration 0.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF BACK INJURY

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF BACK INJURY

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF BACK INJURY

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF BACK INJURY

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication TRIMETHOPRIM /
SULFAMETHOXAZOLE

Prophylaxis Yes ☒
No ☐

Indication ANTIBIOTIC/ PREVENT
INFECTION

Dose per administration 80/400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 13 Apr 2021 22:23:25

Generated On: 09 Jun 2021 14:51:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Feb 2021 00:33:58

Generated On: 09 Jun 2021 14:51:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	BACK SURGERY	Adverse Event	

US3022276

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:51:30

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3022276

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:30

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

SAEID	USA-US051-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

SAEID	USA-US051-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/OCT/2020 16:43
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

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

SAEID	USA-US051-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/OCT/2020 16:18
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

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Feb 2021 00:33:59

Generated On: 09 Jun 2021 14:51:30

SAEID	USA-US051-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 22:58
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

US3022276 (Prod: Meridian Clinical Research-Savannah)

US3022276

Form: Participant Creation

Generated On: 09 Jun 2021 14:51:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'US3022276'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 17:59:34

US3022276

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:46:49
	(b) (4)	

US3022276

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 AUG 2020'	RWS_ENDPOINT	21 Aug 2020 17:59:35
	ENDPOINT (b) (4)	
	(b) (4)	

US3022276

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	21 Aug 2020 22:46:49
	(b) (4)	

US3022276

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered 'SCRN'	(b) (4), (b) (6) System	21 Aug 2020 22:46:49

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered (b) (6)1975'	RWS_ENDPOINT	21 Aug 2020 17:59:36
	ENDPOINT (b) (4)	
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '45'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'YEARS'	(b) (4), (b) (6) System	21 Aug 2020 22:47:18

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '45'	(b) (4), (b) (6) System	21 Aug 2020 20:46:28

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Female (F)'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'PUERTO RICAN'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:18
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Aug 2020'	(b) (4), (b) (6) System	21 Aug 2020 20:46:28

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 20:46:28

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	21 Aug 2020 20:46:28
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Aug 2020 17:59:35
	ENDPOINT (b) (4)	
	(b) (4)	

US3022276

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 20:46:34

US3022276

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:51:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	21 Aug 2020 20:46:34
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:51:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:45
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:48:43
User entered 'TYPE 2 DIABETES'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2004' reason for change:	Stella Yoon (b) (4)	01 Oct 2020 18:21:42
Data Entry Error	(b) (4)	
User entered 'UN UNK 2005'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:47:58
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2004'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:21:42
User entered 'Jan 2005'	System	21 Aug 2020 22:47:58

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2004'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:21:42
User entered '2005'	System	21 Aug 2020 22:47:58

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:47:58

US3022276

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:47:58

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 22:49:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:49:21
Data point term sent to Coder	System	21 Aug 2020 22:48:43
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 22:48:16

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:16
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:16
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:16
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:48:16
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:16
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:16

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:16

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:16

US3022276

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:16

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:48:46
User entered 'ANXIETY'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:26
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:26

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:26

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:26

US3022276

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:26

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:48:44
User entered 'BIPOLAR DISORDER'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:38
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:38

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:38

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:38

US3022276

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:38

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
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)	21 Aug 2020 22:50:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:49:46
User entered 'DEPRESSION'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:48:47
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:47

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2003'	(b) (4), (b) (6) System	21 Aug 2020 22:48:47

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:47

US3022276

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:48:47

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:49:46
User entered 'ASTHMA'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 1992'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:00
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 1992'	(b) (4), (b) (6) System	21 Aug 2020 22:49:00

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '1992'	(b) (4), (b) (6) System	21 Aug 2020 22:49:00

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:00

US3022276

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:00

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
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)	21 Aug 2020 22:50:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:49:46
User entered 'SEASONAL ALLERGIES'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 1996'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:14
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 1996'	(b) (4), (b) (6) System	21 Aug 2020 22:49:14

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '1996'	(b) (4), (b) (6) System	21 Aug 2020 22:49:14

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:14

US3022276

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:14

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:49:46
User entered 'ACNE'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 1986'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:21
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 1986'	(b) (4), (b) (6) System	21 Aug 2020 22:49:21

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '1986'	(b) (4), (b) (6) System	21 Aug 2020 22:49:21

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:21

US3022276

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:21

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
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)	21 Aug 2020 22:50:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:50:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:49:47
User entered 'OSTEOARTHRITIS'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:35
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2003'	(b) (4), (b) (6) System	21 Aug 2020 22:49:35

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2003'	(b) (4), (b) (6) System	21 Aug 2020 22:49:35

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:35

US3022276

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:49:35

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:07:05
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)	07 Oct 2020 15:06:30
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:29:12
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).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:28:30
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:04:14
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)	09 Sep 2020 04:03:30

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:51:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:51:24
Data point term sent to Coder	System	21 Aug 2020 22:50:47
User entered 'PARTIAL HYSTERECTOMY'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 22:49:52

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2004' reason for change:	Stella Yoon (b) (4)	01 Oct 2020 18:29:02
Data Entry Error	(b) (4)	
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:52
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:52
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:52
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2004' reason for change:	Stella Yoon (b) (4)	01 Oct 2020 18:29:02
Data Entry Error	(b) (4)	
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:52
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:49:52
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2004'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:29:02
User entered 'Jan 2015'	System	21 Aug 2020 22:49:52

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User entered '2004'	System	01 Oct 2020 18:29:02
User entered '2015'	System	21 Aug 2020 22:49:52

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2004'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:29:02
User entered 'Jan 2015'	System	21 Aug 2020 22:49:52

US3022276

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User entered '2004'	System	01 Oct 2020 18:29:02
User entered '2015'	System	21 Aug 2020 22:49:52

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Epicondylitis, LLT: Golfer's elbow - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:16:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 23:16:31
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:50:47
User entered 'GOLFERS ELBOW'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:11
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2019'	(b) (4), (b) (6) System	21 Aug 2020 22:50:11

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2019'	(b) (4), (b) (6) System	21 Aug 2020 22:50:11

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:50:11

US3022276

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:50:11

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:51:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:51:24
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:50:48
User entered 'HYPERLIPIDEMIA'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:50:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2019'	(b) (4), (b) (6) System	21 Aug 2020 22:50:32

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2019'	(b) (4), (b) (6) System	21 Aug 2020 22:50:32

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:50:32

US3022276

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:50:32

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:52:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:52:24
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:51:51
User entered 'VITAMIN B-12 DEFICIENCY'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:01
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2019'	(b) (4), (b) (6) System	21 Aug 2020 22:51:01

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2019'	(b) (4), (b) (6) System	21 Aug 2020 22:51:01

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:51:01

US3022276

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:51:01

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Conjunctival infections, irritations and inflammations, PT: Conjunctivitis allergic, LLT: Allergic conjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:52:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 22:52:25
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 22:51:51
User entered 'ALLERGIC CONJUNCTIVITIS'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 1996'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:51:18
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 1996'	(b) (4), (b) (6) System	21 Aug 2020 22:51:18

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '1996'	(b) (4), (b) (6) System	21 Aug 2020 22:51:18

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:51:18

US3022276

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 22:51:18

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 01:36:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 01:36:39
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 01:35:37
User entered 'POST MENOPAUSAL'	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2015'	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	24 Sep 2020 01:35:09
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2015'	(b) (4), (b) (6) System	24 Sep 2020 01:35:09

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2015'	(b) (4), (b) (6) System	24 Sep 2020 01:35:09

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 01:35:09

US3022276

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 01:35:09

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:18:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:18:04
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 18:12:00
User entered 'endometriosis'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2002'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2015' reason for change:	Stella Yoon (b) (4)	01 Oct 2020 18:11:37
Data Entry Error	(b) (4)	
User entered 'un UNK 2004'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:11:32
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2002'	(b) (4), (b) (6) System	01 Oct 2020 18:11:32

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2002'	(b) (4), (b) (6) System	01 Oct 2020 18:11:32

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2015'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:11:37
User entered 'Jan 2004'	System	01 Oct 2020 18:11:32

US3022276

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2015'	(b) (4), (b) (6)	
	System	01 Oct 2020 18:11:37
User entered '2004'	System	01 Oct 2020 18:11:32

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:23:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:23:07
User closed query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYSTS were benign or malignant. 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)	19 Nov 2020 09:45:15
Data point term sent to Coder	System	13 Nov 2020 20:43:15
Query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYSTS were benign or malignant. 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).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:42:53
User entered 'OVARIAN CYSTS - BILATERAL Benign' reason for change: Data Entry Error	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:42:47
User opened query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYSTS were benign or malignant. 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 19:29:38
Data point term sent to Coder	System	01 Oct 2020 18:13:02
User entered 'ovarian cysts - bilateral'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:12:23

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2004'	Stella Yoon (b) (4)	01 Oct 2020 18:12:23
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:12:23
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:12:23
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2015'	Stella Yoon (b) (4)	01 Oct 2020 18:12:23
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:12:23
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2004'	(b) (4), (b) (6) System	01 Oct 2020 18:12:23

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2004'	(b) (4), (b) (6) System	01 Oct 2020 18:12:23

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Oct 2020 18:12:23

US3022276

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2015'	(b) (4), (b) (6) System	01 Oct 2020 18:12:23

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:31:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:31:58
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 18:30:50
User entered 'complete hysterectomy'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2015'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2015'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:29:53
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Oct 2020 18:29:53

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2015'	(b) (4), (b) (6) System	01 Oct 2020 18:29:53

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Oct 2020 18:29:53

US3022276

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2015'	(b) (4), (b) (6) System	01 Oct 2020 18:29:53

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Back injury, LLT: Back injury - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:30:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:30:24
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 12:29:44
User entered 'Back Injury'	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2002'	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 12:28:46
	(b) (4)	

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered 'Jan 2002'	(b) (4), (b) (6) System	09 Oct 2020 12:28:46

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered '2002'	(b) (4), (b) (6) System	09 Oct 2020 12:28:46

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 12:28:46

US3022276

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:51:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 12:28:46

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '13:55'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered '21 Aug 2020 13:55'	(b) (4), (b) (6) System	21 Aug 2020 22:52:01

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '162' cm	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 20:46:34

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '91.2' kg	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 20:46:34

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
Amendment Manager: User entered '34.75080'	(b) (4), (b) (6)	
User entered '34.8'	System	17 Sep 2020 00:18:51
DataPoint set to visible.	System	21 Aug 2020 22:52:01
	System	21 Aug 2020 20:46:34

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	21 Aug 2020 22:52:01
DataPoint set to visible.	System	21 Aug 2020 20:46:34

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 05:59:30
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:08
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:55:53
User entered '37.1' C	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 22:52:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:32:08
	(b) (4)	
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	12 Nov 2020 15:32:08
change Per Query Resolution	(b) (4)	
User entered '75'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 22:52:01

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	12 Nov 2020 15:32:08
change Per Query Resolution	(b) (4)	
User entered '14'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 22:52:01

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:32:08
	(b) (4)	
User entered '128'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 22:52:01

US3022276

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:32:08
	(b) (4)	
User entered '84'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:01
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:09
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 22:52:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:42:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:42:09

US3022276

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:07
	(b) (4)	

US3022276

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 22:52:07
	(b) (4)	

US3022276

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

US3022276

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

US3022276

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:28:46
	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 15:26:22
Query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	24 Sep 2020 01:35:28
	(b) (4)	
User opened query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:48:58
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'un UNK 2004' reason for change:	Stella Yoon (b) (4)	01 Oct 2020 18:28:46
Data Entry Error	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	01 Oct 2020 18:28:46
	(b) (4)	
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 22:58:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'DISABLED VETERAN, SHOPPING'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:30

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

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)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:40:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'LIVES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:14
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:32

US3022276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:32

US3022276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	21 Aug 2020 23:00:32

US3022276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'VISIT1'	System	21 Aug 2020 23:00:32

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:34:35

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '144679'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:34:35

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:34:35

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: Please complete this section of the form, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:37:45
Query 'Per CDM: Please complete this section of the form, otherwise explain.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	31 Aug 2020 12:17:56
User entered 'No (N)'	Shanice Bennett (b) (4)	31 Aug 2020 12:17:46
User opened query 'Per CDM: Please complete this section of the form, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 11:52:15

US3022276

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Shanice Bennett (b) (4)	31 Aug 2020 12:17:46

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 12:17:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 12:17:51
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	31 Aug 2020 12:17:51
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 12:17:46
User entered empty.	Shanice Bennett (b) (4)	31 Aug 2020 12:17:46

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	31 Aug 2020 12:17:46

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Shanice Bennett (b) (4)	31 Aug 2020 12:17:46

US3022276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:59:53
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 18:52:31
User entered 'No (N)'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 18:52:26
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:51:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:07:31

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:50:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:59
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:49
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:32:59
User entered '162' cm	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:32:49
	(b) (4)	
User entered '91.2' kg	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:50:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:59
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:49
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:32:59
User entered '162' cm	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	12 Nov 2020 15:32:49
change Per Query Resolution	(b) (4)	
User entered '91.2' kg	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '13:55'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '21 Aug 2020 13:55'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '37.1' C	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '75'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '14'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '128'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '84'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:50:38
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:59
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 15:32:49
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:32:59
User entered '162' cm	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:01:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:32:49
	(b) (4)	
User entered '91.2' kg	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '16:47'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '21 Aug 2020 16:47'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '37.2' C	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (Oral)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '73'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:49
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '14'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '112'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '83'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 23:01:49

US3022276

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:01:54

US3022276

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 23:01:54
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 20:47:44
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 20:47:44
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 Aug 2020'	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '16:16'	(b) (4) Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '21 Aug 2020 16:16'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'ONCE'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:02:06

US3022276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '21 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:02:06

US3022276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '15:14'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:06
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '21 Aug 2020 15:14'	(b) (4), (b) (6) System	21 Aug 2020 23:02:06

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '21 Aug 2020'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:02:21

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '14:45'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '21 Aug 2020 14:45'	(b) (4), (b) (6) System	21 Aug 2020 23:02:21

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:02:21
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 23:02:21

US3022276

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:02:45
	(b) (4)	

US3022276

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 23:02:45

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:47:57', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '989464c3-d818-4881-b67e-6c6b5ab0a7ad' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:28
	System	21 Aug 2020 20:48:28

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '989464c3-d818-4881-b67e-6c6b5ab0a7ad' User entered '99.0'	(b) (4), (b) (6) System	21 Aug 2020 20:48:28
	System	21 Aug 2020 20:48:28

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:19', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '989464c3-d818-4881-b67e-6c6b5ab0a7ad' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:28
	System	21 Aug 2020 20:48:28

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '989464c3-d818-4881-b67e-6c6b5ab0a7ad' User entered '21 Aug 2020 16:48'	(b) (4), (b) (6) System	21 Aug 2020 20:48:28
	System	21 Aug 2020 20:48:28

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 16:36'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 19:06'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b0a1446d-fe5b-43a2-ad42-03100686d7d3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 00:15:40
	System	22 Aug 2020 00:15:40

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b0a1446d-fe5b-43a2-ad42-03100686d7d3' User entered '99.4'	(b) (4), (b) (6) System	22 Aug 2020 00:15:40
	System	22 Aug 2020 00:15:40

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b0a1446d-fe5b-43a2-ad42-03100686d7d3' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 00:15:40
	System	22 Aug 2020 00:15:40

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b0a1446d-fe5b-43a2-ad42-03100686d7d3' User entered '21 Aug 2020 20:15'	(b) (4), (b) (6) System	22 Aug 2020 00:15:40
	System	22 Aug 2020 00:15:40

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 20:01'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 2'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:06', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '760f27f3-487e-461e-8eda-c1b09e52d534' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 16:10:22
	System	22 Aug 2020 16:10:22

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:12', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '760f27f3-487e-461e-8eda-c1b09e52d534' User entered '97.3'	(b) (4), (b) (6) System	22 Aug 2020 16:10:22
	System	22 Aug 2020 16:10:22

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '760f27f3-487e-461e-8eda-c1b09e52d534'	(b) (4), (b) (6)	
System		22 Aug 2020 16:10:22
User entered 'No (N)'	System	22 Aug 2020 16:10:22

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '760f27f3-487e-461e-8eda-c1b09e52d534' User entered '22 Aug 2020 12:10'	(b) (4), (b) (6) System	22 Aug 2020 16:10:22
	System	22 Aug 2020 16:10:22

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 3'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:09', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3cd9cd9c-906c-40bc-a70d-559f64192b49' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 16:03:26
	System	23 Aug 2020 16:03:26

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3cd9cd9c-906c-40bc-a70d-559f64192b49' User entered '99.4'	(b) (4), (b) (6) System	23 Aug 2020 16:03:26
	System	23 Aug 2020 16:03:26

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3cd9cd9c-906c-40bc-a70d-559f64192b49'	(b) (4), (b) (6)	
System		23 Aug 2020 16:03:26
User entered 'No (N)'	System	23 Aug 2020 16:03:26

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3cd9cd9c-906c-40bc-a70d-559f64192b49' User entered '23 Aug 2020 12:03'	(b) (4), (b) (6) System	23 Aug 2020 16:03:26
	System	23 Aug 2020 16:03:26

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 4'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '57d7fb95-b064-4dfa-8991-91203b13d3d8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 16:04:43
	System	24 Aug 2020 16:04:43

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:33', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '57d7fb95-b064-4dfa-8991-91203b13d3d8' User entered '93.1'	(b) (4), (b) (6) System	24 Aug 2020 16:04:43
	System	24 Aug 2020 16:04:43

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '57d7fb95-b064-4dfa-8991-91203b13d3d8' User entered 'No (N)'	System	24 Aug 2020 16:04:43
	System	24 Aug 2020 16:04:43

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:41', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '57d7fb95-b064-4dfa-8991-91203b13d3d8' User entered '24 Aug 2020 12:04'	(b) (4), (b) (6) System	24 Aug 2020 16:04:43
	System	24 Aug 2020 16:04:43

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 5'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:49:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4aff83cf-389c-4417-8458-b34fc1818550' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:07
	System	25 Aug 2020 17:50:07

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:49:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4aff83cf-389c-4417-8458-b34fc1818550' User entered '96.1'	(b) (4), (b) (6) System	25 Aug 2020 17:50:07
	System	25 Aug 2020 17:50:07

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:49:57', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4aff83cf-389c-4417-8458-b34fc1818550'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:50:07
User entered 'No (N)'	System	25 Aug 2020 17:50:07

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4aff83cf-389c-4417-8458-b34fc1818550' User entered '25 Aug 2020 13:50'	(b) (4), (b) (6) System	25 Aug 2020 17:50:07
	System	25 Aug 2020 17:50:07

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 6'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b4605d4a-a456-4e1c-8fc3-2779cedcd024' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:44
	System	26 Aug 2020 22:32:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b4605d4a-a456-4e1c-8fc3-2779cedcd024' User entered '98.3'	(b) (4), (b) (6) System	26 Aug 2020 22:32:44
	System	26 Aug 2020 22:32:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:39', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b4605d4a-a456-4e1c-8fc3-2779cedcd024' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:44
	System	26 Aug 2020 22:32:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'b4605d4a-a456-4e1c-8fc3-2779cedcd024' User entered '26 Aug 2020 18:32'	(b) (4), (b) (6) System	26 Aug 2020 22:32:44
	System	26 Aug 2020 22:32:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 7'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7b95dd06-f42d-4da1-99d5-e8f12a2277a2' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 21:25:46
	System	27 Aug 2020 21:25:46

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7b95dd06-f42d-4da1-99d5-e8f12a2277a2' User entered '98.7'	(b) (4), (b) (6) System	27 Aug 2020 21:25:46
	System	27 Aug 2020 21:25:46

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7b95dd06-f42d-4da1-99d5-e8f12a2277a2'	(b) (4), (b) (6)	
	System	27 Aug 2020 21:25:46
User entered 'No (N)'	System	27 Aug 2020 21:25:46

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:41', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7b95dd06-f42d-4da1-99d5-e8f12a2277a2' User entered '27 Aug 2020 17:25'	(b) (4), (b) (6) System	27 Aug 2020 21:25:46
	System	27 Aug 2020 21:25:46

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:34', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '71829c7d-d9bc-44e9-b76a-45160434d8c1' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:50
	System	21 Aug 2020 20:48:50

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '71829c7d-d9bc-44e9-b76a-45160434d8c1' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:50
	System	21 Aug 2020 20:48:50

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:40', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '71829c7d-d9bc-44e9-b76a-45160434d8c1' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:50
	System	21 Aug 2020 20:48:50

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:44', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '71829c7d-d9bc-44e9-b76a-45160434d8c1' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 20:48:50
	System	21 Aug 2020 20:48:50

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '71829c7d-d9bc-44e9-b76a-45160434d8c1' User entered '21 Aug 2020 16:48'	(b) (4), (b) (6) System	21 Aug 2020 20:48:50
	System	21 Aug 2020 20:48:50

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 16:36'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 19:06'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:45', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e54def6f-85c6-44d8-a2b4-d19132ffa81e' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:00
	System	22 Aug 2020 00:16:00

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e54def6f-85c6-44d8-a2b4-d19132ffa81e' User entered 'No (N)'	System	22 Aug 2020 00:16:00
	System	22 Aug 2020 00:16:00

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e54def6f-85c6-44d8-a2b4-d19132ffa81e' User entered 'No (N)'	System	22 Aug 2020 00:16:00
	System	22 Aug 2020 00:16:00

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e54def6f-85c6-44d8-a2b4-d19132ffa81e' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:00
	System	22 Aug 2020 00:16:00

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:15:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e54def6f-85c6-44d8-a2b4-d19132ffa81e' User entered '21 Aug 2020 20:15'	(b) (4), (b) (6) System	22 Aug 2020 00:16:00
	System	22 Aug 2020 00:16:00

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 20:01'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 2'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e6b23319-07c4-4d79-a046-fb7a62d804a6'	(b) (4), (b) (6)	
	System	22 Aug 2020 16:11:22
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 16:11:22

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e6b23319-07c4-4d79-a046-fb7a62d804a6' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:22
	System	22 Aug 2020 16:11:22

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:10:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e6b23319-07c4-4d79-a046-fb7a62d804a6' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:22
	System	22 Aug 2020 16:11:22

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:12', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e6b23319-07c4-4d79-a046-fb7a62d804a6' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:22
	System	22 Aug 2020 16:11:22

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e6b23319-07c4-4d79-a046-fb7a62d804a6' User entered '22 Aug 2020 12:11'	(b) (4), (b) (6) System	22 Aug 2020 16:11:22
	System	22 Aug 2020 16:11:22

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 3'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c599e37a-8cc5-48e4-b8d7-83f13314b997'	(b) (4), (b) (6)	23 Aug 2020 16:03:47
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 16:03:47

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c599e37a-8cc5-48e4-b8d7-83f13314b997' User entered 'No (N)'	System	23 Aug 2020 16:03:47
	System	23 Aug 2020 16:03:47

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:40', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c599e37a-8cc5-48e4-b8d7-83f13314b997' User entered 'No (N)'	System	23 Aug 2020 16:03:47
	System	23 Aug 2020 16:03:47

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c599e37a-8cc5-48e4-b8d7-83f13314b997'	(b) (4), (b) (6) System	23 Aug 2020 16:03:47
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 16:03:47

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:45', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c599e37a-8cc5-48e4-b8d7-83f13314b997' User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:03:47
	System	23 Aug 2020 16:03:47

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 4'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:46', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5f879b7e-e748-46b2-8f17-dd2b4fbbdc82' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 16:04:58
	System	24 Aug 2020 16:04:58

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5f879b7e-e748-46b2-8f17-dd2b4fbbdc82' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 16:04:58
	System	24 Aug 2020 16:04:58

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5f879b7e-e748-46b2-8f17-dd2b4fbbdc82' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 16:04:58
	System	24 Aug 2020 16:04:58

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5f879b7e-e748-46b2-8f17-dd2b4fbbdc82' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 16:04:58
	System	24 Aug 2020 16:04:58

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5f879b7e-e748-46b2-8f17-dd2b4fbbdc82' User entered '24 Aug 2020 12:04'	System	24 Aug 2020 16:04:58
	System	24 Aug 2020 16:04:58

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 5'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c5a26569-93d4-4d8f-bacd-85dd4e7d14b5' User entered 'None (1)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:15
	System	25 Aug 2020 17:50:15

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:05', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c5a26569-93d4-4d8f-bacd-85dd4e7d14b5' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:15
	System	25 Aug 2020 17:50:15

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c5a26569-93d4-4d8f-bacd-85dd4e7d14b5' User entered 'No (N)'	System	25 Aug 2020 17:50:15
	System	25 Aug 2020 17:50:15

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c5a26569-93d4-4d8f-bacd-85dd4e7d14b5' User entered 'None (1)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:15
	System	25 Aug 2020 17:50:15

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:10', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c5a26569-93d4-4d8f-bacd-85dd4e7d14b5' User entered '25 Aug 2020 13:50'	System	25 Aug 2020 17:50:15
	System	25 Aug 2020 17:50:15

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 6'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:47', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '68bb61ed-1a19-4f60-aa52-a211a997f5d3' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:56
	System	26 Aug 2020 22:32:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:50', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '68bb61ed-1a19-4f60-aa52-a211a997f5d3' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:56
	System	26 Aug 2020 22:32:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '68bb61ed-1a19-4f60-aa52-a211a997f5d3' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:56
	System	26 Aug 2020 22:32:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '68bb61ed-1a19-4f60-aa52-a211a997f5d3' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 22:32:56
	System	26 Aug 2020 22:32:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '68bb61ed-1a19-4f60-aa52-a211a997f5d3' User entered '26 Aug 2020 18:32'	(b) (4), (b) (6) System	26 Aug 2020 22:32:56
	System	26 Aug 2020 22:32:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 7'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:45', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cb885b63-81e0-4002-b5fd-480c59c3ac69'	(b) (4), (b) (6) System	27 Aug 2020 21:25:56
User entered 'None (1)'	System	27 Aug 2020 21:25:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:48', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cb885b63-81e0-4002-b5fd-480c59c3ac69' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 21:25:56
	System	27 Aug 2020 21:25:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:50', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cb885b63-81e0-4002-b5fd-480c59c3ac69' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 21:25:56
	System	27 Aug 2020 21:25:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cb885b63-81e0-4002-b5fd-480c59c3ac69'	(b) (4), (b) (6)	27 Aug 2020 21:25:56
User entered 'None (1)'	System	27 Aug 2020 21:25:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cb885b63-81e0-4002-b5fd-480c59c3ac69' User entered '27 Aug 2020 17:25'	(b) (4), (b) (6) System	27 Aug 2020 21:25:56
	System	27 Aug 2020 21:25:56

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:57', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:48:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:49:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:49:04', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:49:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:49:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T16:49:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '1a61098c-c067-476d-a02f-459dfd23a85d' User entered '21 Aug 2020 16:49'	(b) (4), (b) (6) System	21 Aug 2020 20:49:19
	System	21 Aug 2020 20:49:19

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 16:36'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 19:06'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:12', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:16', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:22', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered 'No (N)'	System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-21T20:16:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c00d9db2-b7f2-4e36-be8b-dfe90da5b44b' User entered '21 Aug 2020 20:16'	(b) (4), (b) (6) System	22 Aug 2020 00:16:34
	System	22 Aug 2020 00:16:34

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '21 Aug 2020 20:01'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 2'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:34', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:36', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:39', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 16:11:45
	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-22T12:11:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babac847-8e7a-4e10-bd7b-2520d44f6f22'	System	22 Aug 2020 16:11:45
User entered '22 Aug 2020 12:11'	System	22 Aug 2020 16:11:45

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 3'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:09:18
Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:30:46
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:38:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513'	System	23 Aug 2020 16:04:17
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:03:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:06', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-23T12:04:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'da07803c-a7b0-45c7-8594-ae53b15df513' User entered '23 Aug 2020 12:04'	(b) (4), (b) (6) System	23 Aug 2020 16:04:17
	System	23 Aug 2020 16:04:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 4'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:04:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:02', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:04', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:05', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-24T12:05:10', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '18f7204c-bb54-48b3-92b8-833857009b2e' User entered '24 Aug 2020 12:05'	(b) (4), (b) (6) System	24 Aug 2020 16:05:11
	System	24 Aug 2020 16:05:11

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 5'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:13', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:15', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:20', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'None (0)'	System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered 'No (N)'	System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-25T13:50:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a94a5551-def3-4804-93b4-73286667aa20' User entered '25 Aug 2020 13:50'	(b) (4), (b) (6) System	25 Aug 2020 17:50:28
	System	25 Aug 2020 17:50:28

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 6'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:32:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:04', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:05', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:09', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-26T18:33:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7dd2c678-682c-4718-8433-ff4ef0be4082' User entered '26 Aug 2020 18:33'	(b) (4), (b) (6) System	26 Aug 2020 22:33:17
	System	26 Aug 2020 22:33:17

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 7'	System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:25:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:05', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:06', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-08-27T17:26:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ea8f28f5-4d8b-4a36-8e96-493e0333f886' User entered '27 Aug 2020 17:26'	(b) (4), (b) (6) System	27 Aug 2020 21:26:20
	System	27 Aug 2020 21:26:20

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:11

US3022276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '31 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:11

US3022276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:11

US3022276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:01:11
	(b) (4)	

US3022276

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 15:01:25
	(b) (4)	

US3022276

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 15:01:25

US3022276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:37

US3022276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '04 Sep 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 15:01:37

US3022276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:37

US3022276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:01:37
	(b) (4)	

US3022276

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 15:01:40
	(b) (4)	

US3022276

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 15:01:40

US3022276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:01:52

US3022276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:01:52
	(b) (4)	

US3022276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:01:52
	(b) (4)	

US3022276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:01:52
	(b) (4)	

US3022276

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 15:01:57
	(b) (4)	

US3022276

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 15:01:57

US3022276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:46:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit' answered with 'Updated' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:42:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:58:38

US3022276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:58:38

US3022276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:58:38

US3022276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'VISIT2'	(b) (4), (b) (6) System	24 Sep 2020 18:58:38

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '09:34'	(b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '24 Sep 2020 09:34'	(b) (4), (b) (6) System	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '37.1' C	(b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '80'	(b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '120'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '84'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 18:59:11

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '11:18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '24 Sep 2020 11:18'	(b) (4), (b) (6) System	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '37.0' C	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '13'	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '124'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '80'	(b) (4), (b) (6)	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 19:00:30

US3022276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:20

US3022276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:59:20

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 15:02:14
	(b) (4)	

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 15:02:14
	(b) (4)	

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '24 Sep 2020'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '10:46'	Chevon Roberts (b) (4)	24 Sep 2020 15:02:14
	(b) (4)	

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '24 Sep 2020 10:46'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'ONCE'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:40

US3022276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:59:40

US3022276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '09:55'	(b) (4), (b) (6)	24 Sep 2020 18:59:40

US3022276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '24 Sep 2020 09:55'	(b) (4), (b) (6) System	24 Sep 2020 18:59:40

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '10:06'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '24 Sep 2020 10:06'	(b) (4), (b) (6) System	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:59:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:55
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:59:52
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 18:59:52

US3022276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 19:00:00

US3022276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 19:00:00

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:19:43', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '2b66e4bf-0439-43b4-b56f-0126c5c1999e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:06
	System	24 Sep 2020 15:20:06

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:19:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '2b66e4bf-0439-43b4-b56f-0126c5c1999e' User entered '98.7'	(b) (4), (b) (6) System	24 Sep 2020 15:20:06
	System	24 Sep 2020 15:20:06

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:19:57', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '2b66e4bf-0439-43b4-b56f-0126c5c1999e' User entered 'No (N)'	System	24 Sep 2020 15:20:06
	System	24 Sep 2020 15:20:06

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '2b66e4bf-0439-43b4-b56f-0126c5c1999e' User entered '24 Sep 2020 11:20'	(b) (4), (b) (6) System	24 Sep 2020 15:20:06
	System	24 Sep 2020 15:20:06

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 11:06'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 13:36'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4d10e266-5070-4bac-9b1a-484baf8b670e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:35
	System	24 Sep 2020 18:38:35

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4d10e266-5070-4bac-9b1a-484baf8b670e' User entered '99.1'	(b) (4), (b) (6) System	24 Sep 2020 18:38:35
	System	24 Sep 2020 18:38:35

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4d10e266-5070-4bac-9b1a-484baf8b670e' User entered 'No (N)'	System	24 Sep 2020 18:38:35
	System	24 Sep 2020 18:38:35

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4d10e266-5070-4bac-9b1a-484baf8b670e' User entered '24 Sep 2020 14:38'	(b) (4), (b) (6) System	24 Sep 2020 18:38:35
	System	24 Sep 2020 18:38:35

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 14:31'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 2'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:56:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:56:47', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90' User entered '98.6'	(b) (4), (b) (6) System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:56:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 15:16:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Stella Yoon (b) (4)	01 Oct 2020 18:30:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90'	(b) (4)	
User entered '1'	System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 15:16:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Stella Yoon (b) (4)	01 Oct 2020 18:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90'	(b) (4)	
User entered '1'	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '6c963eec-e08f-460d-8a69-d4ee2d8abc90' User entered '25 Sep 2020 12:57'	(b) (4), (b) (6) System	25 Sep 2020 16:57:15
	System	25 Sep 2020 16:57:15

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 3'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:16', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd9bd84e3-2b03-4d86-805a-b87b1d6ec74b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 17:00:34
	System	26 Sep 2020 17:00:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd9bd84e3-2b03-4d86-805a-b87b1d6ec74b' User entered '98.7'	(b) (4), (b) (6) System	26 Sep 2020 17:00:34
	System	26 Sep 2020 17:00:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd9bd84e3-2b03-4d86-805a-b87b1d6ec74b' User entered 'No (N)'	System	26 Sep 2020 17:00:34
	System	26 Sep 2020 17:00:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:28', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd9bd84e3-2b03-4d86-805a-b87b1d6ec74b' User entered '26 Sep 2020 13:00'	(b) (4), (b) (6) System	26 Sep 2020 17:00:34
	System	26 Sep 2020 17:00:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 4'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd24f196f-32af-4657-b96e-421b2b33adf5'	(b) (4), (b) (6)	
	System	27 Sep 2020 18:40:34
User entered 'Yes (Y)'	System	27 Sep 2020 18:40:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:22', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd24f196f-32af-4657-b96e-421b2b33adf5' User entered '98.6'	(b) (4), (b) (6) System	27 Sep 2020 18:40:34
	System	27 Sep 2020 18:40:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd24f196f-32af-4657-b96e-421b2b33adf5'	(b) (4), (b) (6)	
System		27 Sep 2020 18:40:34
User entered 'No (N)'	System	27 Sep 2020 18:40:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd24f196f-32af-4657-b96e-421b2b33adf5'	(b) (4), (b) (6)	
	System	27 Sep 2020 18:40:34
User entered '27 Sep 2020 14:40'	System	27 Sep 2020 18:40:34

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 5'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:52:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f5e2319e-3b1f-471c-8417-c02724cd40ba' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:09
	System	28 Sep 2020 17:53:09

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f5e2319e-3b1f-471c-8417-c02724cd40ba' User entered '98.8'	(b) (4), (b) (6) System	28 Sep 2020 17:53:09
	System	28 Sep 2020 17:53:09

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f5e2319e-3b1f-471c-8417-c02724cd40ba' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:09
	System	28 Sep 2020 17:53:09

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:06', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f5e2319e-3b1f-471c-8417-c02724cd40ba' User entered '28 Sep 2020 13:53'	(b) (4), (b) (6) System	28 Sep 2020 17:53:09
	System	28 Sep 2020 17:53:09

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 6'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:10', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b9722f1-a5e5-4d7f-93ed-f692664f8918' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:22
	System	30 Sep 2020 00:29:22

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:15', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b9722f1-a5e5-4d7f-93ed-f692664f8918' User entered '98.7'	(b) (4), (b) (6) System	30 Sep 2020 00:29:22
	System	30 Sep 2020 00:29:22

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b9722f1-a5e5-4d7f-93ed-f692664f8918'	(b) (4), (b) (6)	
	System	30 Sep 2020 00:29:22
User entered 'No (N)'	System	30 Sep 2020 00:29:22

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:20', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b9722f1-a5e5-4d7f-93ed-f692664f8918' User entered '29 Sep 2020 20:29'	(b) (4), (b) (6) System	30 Sep 2020 00:29:22
	System	30 Sep 2020 00:29:22

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 7'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:33', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '95941845-1612-43d5-ba82-2f555211cb53'	(b) (4), (b) (6)	
	System	30 Sep 2020 22:09:51
User entered 'Yes (Y)'	System	30 Sep 2020 22:09:51

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:41', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '95941845-1612-43d5-ba82-2f555211cb53' User entered '98.9'	(b) (4), (b) (6) System	30 Sep 2020 22:09:51
	System	30 Sep 2020 22:09:51

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:44', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '95941845-1612-43d5-ba82-2f555211cb53'	(b) (4), (b) (6)	
System		30 Sep 2020 22:09:51
User entered 'No (N)'	System	30 Sep 2020 22:09:51

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:46', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '95941845-1612-43d5-ba82-2f555211cb53'	(b) (4), (b) (6)	
	System	30 Sep 2020 22:09:51
User entered '30 Sep 2020 18:09'	System	30 Sep 2020 22:09:51

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '38943dce-c717-479d-a1b6-5885ab215d8c'	(b) (4), (b) (6)	
	System	24 Sep 2020 15:20:20
User entered 'None (1)'	System	24 Sep 2020 15:20:20

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:10', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '38943dce-c717-479d-a1b6-5885ab215d8c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:20
	System	24 Sep 2020 15:20:20

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:12', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '38943dce-c717-479d-a1b6-5885ab215d8c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:20
	System	24 Sep 2020 15:20:20

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '38943dce-c717-479d-a1b6-5885ab215d8c'	(b) (4), (b) (6)	
	System	24 Sep 2020 15:20:20
User entered 'None (1)'	System	24 Sep 2020 15:20:20

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '38943dce-c717-479d-a1b6-5885ab215d8c' User entered '24 Sep 2020 11:20'	(b) (4), (b) (6) System	24 Sep 2020 15:20:20
	System	24 Sep 2020 15:20:20

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 11:06'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 13:36'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '39a20823-06a5-4cf2-be1e-0f6325e5a215'	(b) (4), (b) (6)	
	System	24 Sep 2020 18:38:53
User entered 'None (1)'	System	24 Sep 2020 18:38:53

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:41', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '39a20823-06a5-4cf2-be1e-0f6325e5a215' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:53
	System	24 Sep 2020 18:38:53

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:43', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '39a20823-06a5-4cf2-be1e-0f6325e5a215' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:53
	System	24 Sep 2020 18:38:53

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:46', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '39a20823-06a5-4cf2-be1e-0f6325e5a215'	(b) (4), (b) (6)	24 Sep 2020 18:38:53
User entered 'None (1)'	System	24 Sep 2020 18:38:53

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:38:48', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '39a20823-06a5-4cf2-be1e-0f6325e5a215' User entered '24 Sep 2020 14:38'	(b) (4), (b) (6) System	24 Sep 2020 18:38:53
	System	24 Sep 2020 18:38:53

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 14:31'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 2'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '77657826-ed25-4639-9b0b-049db29029a4'	(b) (4), (b) (6)	25 Sep 2020 16:57:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	25 Sep 2020 16:57:57

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '77657826-ed25-4639-9b0b-049db29029a4' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:57:57
	System	25 Sep 2020 16:57:57

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '77657826-ed25-4639-9b0b-049db29029a4' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:57:57
	System	25 Sep 2020 16:57:57

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:36', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '77657826-ed25-4639-9b0b-049db29029a4'	(b) (4), (b) (6)	
User entered 'None (1)'	System	25 Sep 2020 16:57:57

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:57:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '77657826-ed25-4639-9b0b-049db29029a4' User entered '25 Sep 2020 12:57'	(b) (4), (b) (6) System	25 Sep 2020 16:57:57
	System	25 Sep 2020 16:57:57

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 3'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'af45cd9e-f459-4183-ae24-8dbcae9e8101' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 17:00:52
	System	26 Sep 2020 17:00:52

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'af45cd9e-f459-4183-ae24-8dbcae9e8101' User entered 'No (N)'	System	26 Sep 2020 17:00:52
	System	26 Sep 2020 17:00:52

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'af45cd9e-f459-4183-ae24-8dbcae9e8101' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 17:00:52
	System	26 Sep 2020 17:00:52

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:39', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'af45cd9e-f459-4183-ae24-8dbcae9e8101' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 17:00:52
	System	26 Sep 2020 17:00:52

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:41', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'af45cd9e-f459-4183-ae24-8dbcae9e8101' User entered '26 Sep 2020 13:00'	(b) (4), (b) (6) System	26 Sep 2020 17:00:52
	System	26 Sep 2020 17:00:52

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 4'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b95d7c9-8ebc-4978-b247-f1fbaa8f43ed'	(b) (4), (b) (6)	
	System	27 Sep 2020 18:40:46
User entered 'None (1)'	System	27 Sep 2020 18:40:46

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b95d7c9-8ebc-4978-b247-f1fbaa8f43ed' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 18:40:46
	System	27 Sep 2020 18:40:46

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:39', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b95d7c9-8ebc-4978-b247-f1fbaa8f43ed' User entered 'No (N)'	System	27 Sep 2020 18:40:46
	System	27 Sep 2020 18:40:46

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:40', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b95d7c9-8ebc-4978-b247-f1fbaa8f43ed'	(b) (4), (b) (6)	
	System	27 Sep 2020 18:40:46
User entered 'None (1)'	System	27 Sep 2020 18:40:46

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:43', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '9b95d7c9-8ebc-4978-b247-f1fbaa8f43ed' User entered '27 Sep 2020 14:40'	(b) (4), (b) (6) System	27 Sep 2020 18:40:46
	System	27 Sep 2020 18:40:46

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 5'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:09', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e91d3807-2750-47d4-bdc9-27ed94684a19'	(b) (4), (b) (6) System	28 Sep 2020 17:53:21
User entered 'None (1)'	System	28 Sep 2020 17:53:21

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:12', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e91d3807-2750-47d4-bdc9-27ed94684a19' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:21
	System	28 Sep 2020 17:53:21

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:13', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e91d3807-2750-47d4-bdc9-27ed94684a19'	(b) (4), (b) (6) System	28 Sep 2020 17:53:21
User entered 'No (N)'	System	28 Sep 2020 17:53:21

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e91d3807-2750-47d4-bdc9-27ed94684a19'	(b) (4), (b) (6) System	28 Sep 2020 17:53:21
User entered 'None (1)'	System	28 Sep 2020 17:53:21

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:17', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e91d3807-2750-47d4-bdc9-27ed94684a19' User entered '28 Sep 2020 13:53'	(b) (4), (b) (6) System	28 Sep 2020 17:53:21
	System	28 Sep 2020 17:53:21

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 6'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c78a6095-59c4-4ab9-af24-5cab922f7a19'	(b) (4), (b) (6)	
User entered 'None (1)'	System	30 Sep 2020 00:29:32

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c78a6095-59c4-4ab9-af24-5cab922f7a19' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:32
	System	30 Sep 2020 00:29:32

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c78a6095-59c4-4ab9-af24-5cab922f7a19' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:32
	System	30 Sep 2020 00:29:32

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:28', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c78a6095-59c4-4ab9-af24-5cab922f7a19'	(b) (4), (b) (6)	
	System	30 Sep 2020 00:29:32
User entered 'None (1)'	System	30 Sep 2020 00:29:32

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:30', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'c78a6095-59c4-4ab9-af24-5cab922f7a19' User entered '29 Sep 2020 20:29'	(b) (4), (b) (6) System	30 Sep 2020 00:29:32
	System	30 Sep 2020 00:29:32

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 7'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '98c300ed-8c67-48b8-9abc-398f96f0bd0a' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:04
	System	30 Sep 2020 22:10:04

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '98c300ed-8c67-48b8-9abc-398f96f0bd0a' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:04
	System	30 Sep 2020 22:10:04

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '98c300ed-8c67-48b8-9abc-398f96f0bd0a' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:04
	System	30 Sep 2020 22:10:04

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '98c300ed-8c67-48b8-9abc-398f96f0bd0a' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:04
	System	30 Sep 2020 22:10:04

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:09:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '98c300ed-8c67-48b8-9abc-398f96f0bd0a' User entered '30 Sep 2020 18:09'	(b) (4), (b) (6) System	30 Sep 2020 22:10:04
	System	30 Sep 2020 22:10:04

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:28', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:36', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T11:20:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '322f00e0-9e70-4d1a-88e8-031ef3c8ee3a' User entered '24 Sep 2020 11:20'	(b) (4), (b) (6) System	24 Sep 2020 15:20:40
	System	24 Sep 2020 15:20:40

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 11:06'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 13:36'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:02', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:04', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:05', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:09', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-24T14:39:13', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8806b03f-59cb-4b7c-829b-ee49b154f4ec' User entered '24 Sep 2020 14:39'	(b) (4), (b) (6) System	24 Sep 2020 18:39:16
	System	24 Sep 2020 18:39:16

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '24 Sep 2020 14:31'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 2'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:16', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca'	(b) (4), (b) (6)	
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:58:52
User entered 'Some interference with activity (2)'	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:58:52
User entered 'Some interference with activity (2)'	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:58:52
User entered 'Some interference with activity (2)'	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca'	(b) (4), (b) (6)	
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:39', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca' User entered 'None (0)'	System	25 Sep 2020 16:58:52
	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:46', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:58:52
	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-25T12:58:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a3ef75f9-bf73-41fa-a574-00fa9af392ca' User entered '25 Sep 2020 12:58'	(b) (4), (b) (6) System	25 Sep 2020 16:58:52
	System	25 Sep 2020 16:58:52

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 3'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:46', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:48', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:53', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:00:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'None (0)'	System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:01:04', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered 'No (N)'	System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-26T13:01:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '25216e55-c283-497f-a8de-bd49eea39b95' User entered '26 Sep 2020 13:01'	(b) (4), (b) (6) System	26 Sep 2020 17:01:39
	System	26 Sep 2020 17:01:39

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 4'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:47', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:51', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:53', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:40:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-27T14:41:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '37915251-7b7c-4a60-b39c-678029515496' User entered '27 Sep 2020 14:41'	(b) (4), (b) (6) System	27 Sep 2020 18:41:03
	System	27 Sep 2020 18:41:03

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 5'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:20', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:22', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'None (0)'	System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-28T13:53:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4f8915ed-9b11-458a-b001-083f9aa07dcf' User entered '28 Sep 2020 13:53'	(b) (4), (b) (6) System	28 Sep 2020 17:53:34
	System	28 Sep 2020 17:53:34

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 6'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:33', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:34', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:36', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:38', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'None (0)'	System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:40', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered 'No (N)'	System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-29T20:29:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '578e1ebd-b35d-49d7-94b3-448f32f5414b' User entered '29 Sep 2020 20:29'	(b) (4), (b) (6) System	30 Sep 2020 00:29:46
	System	30 Sep 2020 00:29:46

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 15:02:14
User entered 'Day 7'	System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae'	(b) (4), (b) (6)	
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:18', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'None (0)'	System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:20', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-09-30T18:10:32', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f146e27c-9f0e-4e90-9238-48bbf2eff5ae' User entered '30 Sep 2020 18:10'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36
	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 15:02:14

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	30 Sep 2020 22:10:36
User entered 'Day 8'	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-01T22:19:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '312288e1-6c25-445a-b35e-85e0c4a773d5' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 02:19:28
	System	02 Oct 2020 02:19:28

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-01T22:19:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '312288e1-6c25-445a-b35e-85e0c4a773d5' User entered '01 Oct 2020 22:19'	(b) (4), (b) (6) System	02 Oct 2020 02:19:28
	System	02 Oct 2020 02:19:28

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
Data entry locked.	(b) (4), (b) (6)	
	System	30 Sep 2020 22:10:36
User entered 'Day 8'	System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-01T22:19:33', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8c45997e-5f4d-4337-9f32-5f178ee3c5dc' User entered 'No (N)'	System	02 Oct 2020 02:19:38
	System	02 Oct 2020 02:19:38

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-01T22:19:36', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '8c45997e-5f4d-4337-9f32-5f178ee3c5dc' User entered '01 Oct 2020 22:19'	(b) (4), (b) (6) System	02 Oct 2020 02:19:38
	System	02 Oct 2020 02:19:38

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36

US3022276

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:51:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	30 Sep 2020 22:10:36

US3022276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:18:20

US3022276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:18:20

US3022276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:18:20

US3022276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:18:20

US3022276

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:18:26

US3022276

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 19:18:26

US3022276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:25:55

US3022276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:25:55

US3022276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:25:55

US3022276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:25:55

US3022276

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:26:02

US3022276

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	09 Oct 2020 14:26:02

US3022276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:13

US3022276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '15 Oct 2020'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:13

US3022276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Deal (b) (4)	13 Nov 2020 20:40:13

US3022276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Morgan Deal (b) (4)	13 Nov 2020 20:40:13
	(b) (4)	

US3022276

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:16

US3022276

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	13 Nov 2020 20:40:16

US3022276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:28

US3022276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '23 Oct 2020'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:28

US3022276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Clinic (Clinic)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:40:28

US3022276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'VISIT3'	(b) (4), (b) (6) System	13 Nov 2020 20:40:28

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '23 Oct 2020'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '10:35'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '23 Oct 2020 10:35'	(b) (4), (b) (6) System	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:26
	(b) (4)	
User entered '36.9' C	Morgan Deal (b) (4)	13 Nov 2020 20:41:08
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Oral (Oral)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:26
	(b) (4)	
User entered empty.	Morgan Deal (b) (4)	13 Nov 2020 20:41:08
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '73'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'bpm'	(b) (4), (b) (6) System	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '15'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '120'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:26
	(b) (4)	
User entered '77'	Morgan Deal (b) (4)	13 Nov 2020 20:41:08
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'mmHg'	(b) (4), (b) (6) System	13 Nov 2020 20:41:08

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:18

US3022276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:26
	(b) (4)	
User entered '23 Oct 2020'	Morgan Deal (b) (4)	13 Nov 2020 20:41:18
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:33

US3022276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:26
User entered '23 Oct 2020'	(b) (4) Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:41:33

US3022276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:26
	(b) (4)	
User entered '10:44'	Morgan Deal (b) (4)	13 Nov 2020 20:41:33
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered '23 Oct 2020 10:44'	(b) (4), (b) (6) System	13 Nov 2020 20:41:33

US3022276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Morgan Deal (b) (4)	13 Nov 2020 20:41:37
	(b) (4)	

US3022276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	13 Nov 2020 20:41:37

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 64'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-23T16:44:15', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3e4cde9b-efdf-4fff-9c92-72e6739d679d' User entered 'No (N)'	(b) (4), (b) (6) System	23 Oct 2020 20:44:28
	System	23 Oct 2020 20:44:28

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-23T16:44:19', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3e4cde9b-efdf-4fff-9c92-72e6739d679d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Oct 2020 20:44:28

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-23T16:44:23', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3e4cde9b-efdf-4fff-9c92-72e6739d679d' User entered '23 Oct 2020 16:44:23'	(b) (4), (b) (6) System	23 Oct 2020 20:44:28
	System	23 Oct 2020 20:44:28

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 71'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-28T08:28:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd36a8d43-1c49-4da4-a370-1bed98e44284' User entered 'No (N)'	(b) (4), (b) (6) System	28 Oct 2020 12:28:57
	System	28 Oct 2020 12:28:57

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-28T08:28:49', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd36a8d43-1c49-4da4-a370-1bed98e44284' User entered 'No (N)'	(b) (4), (b) (6) System	28 Oct 2020 12:28:57
	System	28 Oct 2020 12:28:57

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-10-28T08:28:53', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd36a8d43-1c49-4da4-a370-1bed98e44284' User entered '28 Oct 2020 08:28:53'	(b) (4), (b) (6) System	28 Oct 2020 12:28:57
	System	28 Oct 2020 12:28:57

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 78'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-04T05:17:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e84f875c-c0de-4078-9c83-7bf5f24318b8'	(b) (4), (b) (6)	
	System	04 Nov 2020 10:18:13
User entered 'No (N)'	System	04 Nov 2020 10:18:13

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-04T05:18:07', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e84f875c-c0de-4078-9c83-7bf5f24318b8'	(b) (4), (b) (6)	
	System	04 Nov 2020 10:18:13
User entered 'No (N)'	System	04 Nov 2020 10:18:13

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-04T05:18:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e84f875c-c0de-4078-9c83-7bf5f24318b8' User entered '04 Nov 2020 05:18:11'	(b) (4), (b) (6) System	04 Nov 2020 10:18:13
	System	04 Nov 2020 10:18:13

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered 'Day 92'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-18T04:42:54', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aac96b9c-c91c-480a-883f-6017b37df916'	(b) (4), (b) (6)	
	System	18 Nov 2020 09:43:03
User entered 'No (N)'	System	18 Nov 2020 09:43:03

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-18T04:42:58', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aac96b9c-c91c-480a-883f-6017b37df916'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Nov 2020 09:43:03

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-18T04:43:01', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aac96b9c-c91c-480a-883f-6017b37df916' User entered '18 Nov 2020 04:43:01'	(b) (4), (b) (6) System	18 Nov 2020 09:43:03
	System	18 Nov 2020 09:43:03

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 20:47:44

US3022276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:14:12
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:47:44
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 20:47:44

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-25T07:31:44', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cba77ffe-8bfe-4eae-9378-635399fb331e' User entered 'No (N)'	System	25 Nov 2020 12:31:58

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-25T07:31:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cba77ffe-8bfe-4eae-9378-635399fb331e' User entered 'No (N)'	System	25 Nov 2020 12:31:58

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-25T07:31:56', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'cba77ffe-8bfe-4eae-9378-635399fb331e' User entered '25 Nov 2020 07:31:56'	System	25 Nov 2020 12:31:58
	System	25 Nov 2020 12:31:58

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-29T05:12:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '14f6ee68-30fe-411e-9b86-41679f24425f' User entered 'No (N)'	System	29 Nov 2020 10:12:53

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-29T05:12:45', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '14f6ee68-30fe-411e-9b86-41679f24425f' User entered 'No (N)'	System	29 Nov 2020 10:12:53

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-11-29T05:12:50', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '14f6ee68-30fe-411e-9b86-41679f24425f' User entered '29 Nov 2020 05:12:50'	System	29 Nov 2020 10:12:53
	System	29 Nov 2020 10:12:53

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-06T08:04:14', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '268b3bd3-dc6d-4b8a-a4fa-2778c4d99c8b' User entered 'No (N)'	System	06 Dec 2020 13:04:26
	System	06 Dec 2020 13:04:26

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-06T08:04:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '268b3bd3-dc6d-4b8a-a4fa-2778c4d99c8b' User entered 'No (N)'	System	06 Dec 2020 13:04:26
	System	06 Dec 2020 13:04:26

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-06T08:04:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '268b3bd3-dc6d-4b8a-a4fa-2778c4d99c8b' User entered '06 Dec 2020 08:04:24'	System	06 Dec 2020 13:04:26
	System	06 Dec 2020 13:04:26

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-15T13:06:09', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '63ea13fb-94b2-4771-b534-ff68bcd65c81' User entered 'No (N)'	System	15 Dec 2020 18:06:21
	System	15 Dec 2020 18:06:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-15T13:06:13', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '63ea13fb-94b2-4771-b534-ff68bcd65c81'	System	15 Dec 2020 18:06:21
User entered 'No (N)'	System	15 Dec 2020 18:06:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-15T13:06:16', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '63ea13fb-94b2-4771-b534-ff68bcd65c81' User entered '15 Dec 2020 13:06:16'	System	15 Dec 2020 18:06:21
	System	15 Dec 2020 18:06:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-22T13:08:10', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '790db4af-074d-4592-b1fb-f15ed750c79c'	System	22 Dec 2020 21:08:19
User entered 'No (N)'	System	22 Dec 2020 21:08:19

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-22T13:08:13', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '790db4af-074d-4592-b1fb-f15ed750c79c'	System	22 Dec 2020 21:08:19
User entered 'No (N)'	System	22 Dec 2020 21:08:19

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-22T13:08:15', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '790db4af-074d-4592-b1fb-f15ed750c79c' User entered '22 Dec 2020 13:08:15'	System	22 Dec 2020 21:08:19
	System	22 Dec 2020 21:08:19

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-27T10:47:44', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ab838c3b-befb-40c3-990e-cc36e69f05ac' User entered 'No (N)'	System	27 Dec 2020 18:47:52
	System	27 Dec 2020 18:47:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-27T10:47:47', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ab838c3b-befb-40c3-990e-cc36e69f05ac' User entered 'No (N)'	System	27 Dec 2020 18:47:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0B00F0FF-36DF-44FE-B418-60F204D5D808)', Time: '2020-12-27T10:47:50', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'ab838c3b-befb-40c3-990e-cc36e69f05ac' User entered '27 Dec 2020 10:47:50'	System	27 Dec 2020 18:47:52
	System	27 Dec 2020 18:47:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-07T13:55:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4dfc0b37-a983-495b-acf8-988bbe72ab23'	System	07 Jan 2021 18:56:13
User entered 'No (N)'	System	07 Jan 2021 18:56:13

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-07T13:56:08', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4dfc0b37-a983-495b-acf8-988bbe72ab23'	System	07 Jan 2021 18:56:13
User entered 'No (N)'	System	07 Jan 2021 18:56:13

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-07T13:56:11', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '4dfc0b37-a983-495b-acf8-988bbe72ab23' User entered '07 Jan 2021 13:56:11'	System	07 Jan 2021 18:56:13
	System	07 Jan 2021 18:56:13

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-10T04:57:42', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e04d6922-5e64-46d7-9d66-148ed36c95c2'	System	10 Jan 2021 09:57:50
User entered 'No (N)'	System	10 Jan 2021 09:57:50

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-10T04:57:44', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e04d6922-5e64-46d7-9d66-148ed36c95c2'	System	10 Jan 2021 09:57:50
User entered 'No (N)'	System	10 Jan 2021 09:57:50

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-10T04:57:47', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e04d6922-5e64-46d7-9d66-148ed36c95c2' User entered '10 Jan 2021 04:57:47'	System	10 Jan 2021 09:57:50
	System	10 Jan 2021 09:57:50

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-17T00:07:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a668f3ee-53a8-4ab1-a212-9ea8d5e438c3'	System	17 Jan 2021 05:08:07
User entered 'No (N)'	System	17 Jan 2021 05:08:07

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-17T00:07:59', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a668f3ee-53a8-4ab1-a212-9ea8d5e438c3'	System	17 Jan 2021 05:08:07
User entered 'No (N)'	System	17 Jan 2021 05:08:07

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-17T00:08:03', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'a668f3ee-53a8-4ab1-a212-9ea8d5e438c3' User entered '17 Jan 2021 00:08:03'	System	17 Jan 2021 05:08:07
	System	17 Jan 2021 05:08:07

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-26T19:01:48', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '02621d0e-8bde-4773-9352-d4a7f5f98637'	System	27 Jan 2021 01:03:38
User entered 'No (N)'	System	27 Jan 2021 01:03:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-26T19:01:52', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '02621d0e-8bde-4773-9352-d4a7f5f98637'	System	27 Jan 2021 01:03:38
User entered 'No (N)'	System	27 Jan 2021 01:03:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-26T19:01:55', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '02621d0e-8bde-4773-9352-d4a7f5f98637'	System	27 Jan 2021 01:03:38
User entered '26 Jan 2021 19:01:55'	System	27 Jan 2021 01:03:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-31T04:07:31', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '81d3eaae-a7f5-407a-add7-3fd91ecdac57'	System	31 Jan 2021 09:07:41
User entered 'No (N)'	System	31 Jan 2021 09:07:41

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-31T04:07:34', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '81d3eaae-a7f5-407a-add7-3fd91ecdac57'	System	31 Jan 2021 09:07:41
User entered 'No (N)'	System	31 Jan 2021 09:07:41

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-01-31T04:07:37', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '81d3eaae-a7f5-407a-add7-3fd91ecdac57' User entered '31 Jan 2021 04:07:37'	System	31 Jan 2021 09:07:41
	System	31 Jan 2021 09:07:41

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-09T12:09:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0939a0d3-f015-433a-a556-e2b321999dcc' User entered 'No (N)'	System	09 Feb 2021 17:14:38
	System	09 Feb 2021 17:14:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-09T12:09:28', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0939a0d3-f015-433a-a556-e2b321999dcc' User entered 'No (N)'	System	09 Feb 2021 17:14:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-09T12:09:35', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0939a0d3-f015-433a-a556-e2b321999dcc' User entered '09 Feb 2021 12:09:35'	System	09 Feb 2021 17:14:38
	System	09 Feb 2021 17:14:38

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-16T13:12:25', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '388bcd6d-3b92-4b24-a353-2bb9a9b46d2a' User entered 'No (N)'	System	21 Feb 2021 08:59:22
	System	21 Feb 2021 08:59:22

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-16T13:12:26', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '388bcd6d-3b92-4b24-a353-2bb9a9b46d2a' User entered 'No (N)'	System	21 Feb 2021 08:59:22

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-16T13:12:29', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '388bcd6d-3b92-4b24-a353-2bb9a9b46d2a' User entered '16 Feb 2021 13:12:29'	System	21 Feb 2021 08:59:22

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-21T03:59:21', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e766d3bb-24ea-4394-9445-96463686d4a8'	System	28 Feb 2021 09:03:33
User entered 'No (N)'	System	28 Feb 2021 09:03:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-21T03:59:24', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e766d3bb-24ea-4394-9445-96463686d4a8'	System	28 Feb 2021 09:03:33
User entered 'No (N)'	System	28 Feb 2021 09:03:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-21T03:59:27', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'e766d3bb-24ea-4394-9445-96463686d4a8'	System	28 Feb 2021 09:03:33
User entered '21 Feb 2021 03:59:27'	System	28 Feb 2021 09:03:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-28T04:04:13-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babcf70e-e6c9-4a3d-b759-e770a3fc512b' User entered 'No (N)'	System	28 Feb 2021 09:04:21
	System	28 Feb 2021 09:04:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-28T04:04:15-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babcf70e-e6c9-4a3d-b759-e770a3fc512b' User entered 'No (N)'	System	28 Feb 2021 09:04:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-28T04:04:18-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'babcf70e-e6c9-4a3d-b759-e770a3fc512b' User entered '28 Feb 2021 09:04:18'	System	28 Feb 2021 09:04:21
	System	28 Feb 2021 09:04:21

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-07T05:57:19-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5abf2e19-d827-4fd6-99cf-da45c052042e' User entered 'No (N)'	System	07 Mar 2021 10:57:30
	System	07 Mar 2021 10:57:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-07T05:57:24-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5abf2e19-d827-4fd6-99cf-da45c052042e'	System	07 Mar 2021 10:57:30
User entered 'No (N)'	System	07 Mar 2021 10:57:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-07T05:57:27-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '5abf2e19-d827-4fd6-99cf-da45c052042e' User entered '07 Mar 2021 05:57:27'	System	07 Mar 2021 10:57:30
	System	07 Mar 2021 10:57:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:03:25-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef'	System	16 Mar 2021 21:04:23
User entered 'Yes (Y)'	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:03:19-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef'	System	16 Mar 2021 21:04:23
User entered 'No (N)'	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:03:38-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef'	System	16 Mar 2021 21:04:23
User entered 'No (N)'	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:03:55-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef'	System	16 Mar 2021 21:04:23
User entered 'Yes (Y)'	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:04:03-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef'	System	16 Mar 2021 21:04:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-16T17:04:08-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '3b0ca083-3407-4f5c-aa1b-426e94a559ef' User entered '16 Mar 2021 17:04:08'	System	16 Mar 2021 21:04:23
	System	16 Mar 2021 21:04:23

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-21T10:12:20-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aa9f2b63-e186-4ea3-946f-f1078607f5fa' User entered 'No (N)'	System	21 Mar 2021 14:12:30
	System	21 Mar 2021 14:12:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-21T10:12:22-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aa9f2b63-e186-4ea3-946f-f1078607f5fa' User entered 'No (N)'	System	21 Mar 2021 14:12:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-21T10:12:25-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'aa9f2b63-e186-4ea3-946f-f1078607f5fa' User entered '21 Mar 2021 10:12:25'	System	21 Mar 2021 14:12:30
	System	21 Mar 2021 14:12:30

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-31T11:19:23-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7e56d442-9179-42f9-965a-5e8e194cb6d9' User entered 'No (N)'	System	31 Mar 2021 15:19:33
	System	31 Mar 2021 15:19:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-31T11:19:26-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7e56d442-9179-42f9-965a-5e8e194cb6d9' User entered 'No (N)'	System	31 Mar 2021 15:19:33
	System	31 Mar 2021 15:19:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-03-31T11:19:29-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '7e56d442-9179-42f9-965a-5e8e194cb6d9' User entered '31 Mar 2021 11:19:29'	System	31 Mar 2021 15:19:33
	System	31 Mar 2021 15:19:33

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-04T10:33:45-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f7da4bbc-217b-45a9-8f90-30ba61026849' User entered 'No (N)'	System	04 Apr 2021 14:33:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-04T10:33:46-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f7da4bbc-217b-45a9-8f90-30ba61026849'	System	04 Apr 2021 14:33:52
User entered 'No (N)'	System	04 Apr 2021 14:33:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-04T10:33:49-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'f7da4bbc-217b-45a9-8f90-30ba61026849' User entered '04 Apr 2021 10:33:49'	System	04 Apr 2021 14:33:52
	System	04 Apr 2021 14:33:52

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-11T04:23:44-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '88d9a5ad-7e27-4a5c-974d-27ba772e8dc2'	System	11 Apr 2021 08:24:09
User entered 'No (N)'	System	11 Apr 2021 08:24:09

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-11T04:23:46-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '88d9a5ad-7e27-4a5c-974d-27ba772e8dc2'	System	11 Apr 2021 08:24:09
User entered 'No (N)'	System	11 Apr 2021 08:24:09

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-11T04:24:06-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '88d9a5ad-7e27-4a5c-974d-27ba772e8dc2'	System	11 Apr 2021 08:24:09
User entered '11 Apr 2021 04:24:06'	System	11 Apr 2021 08:24:09

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-18T00:39:30-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd10b4b2e-a142-4137-a05b-f35a1a6ff573'	System	18 Apr 2021 04:39:40
User entered 'No (N)'	System	18 Apr 2021 04:39:40

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-18T00:39:34-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd10b4b2e-a142-4137-a05b-f35a1a6ff573'	System	18 Apr 2021 04:39:40
User entered 'No (N)'	System	18 Apr 2021 04:39:40

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-18T00:39:37-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: 'd10b4b2e-a142-4137-a05b-f35a1a6ff573'	System	18 Apr 2021 04:39:40
User entered '18 Apr 2021 00:39:37'	System	18 Apr 2021 04:39:40

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-25T04:05:28-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '65999096-8760-4a91-ad1f-ef70eff01db9'	System	02 May 2021 08:09:49
User entered 'No (N)'	System	02 May 2021 08:09:49

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-25T04:05:30-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '65999096-8760-4a91-ad1f-ef70eff01db9'	System	02 May 2021 08:09:49
User entered 'No (N)'	System	02 May 2021 08:09:49

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-04-25T04:05:32-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '65999096-8760-4a91-ad1f-ef70eff01db9'	System	02 May 2021 08:09:49
User entered '25 Apr 2021 04:05:32'	System	02 May 2021 08:09:49

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-05-02T04:09:46-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0e8934e1-656f-4bd9-9643-8c2a1e4ac007'	System	02 May 2021 08:09:58
User entered 'No (N)'	System	02 May 2021 08:09:58

US3022276

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-05-02T04:09:52-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0e8934e1-656f-4bd9-9643-8c2a1e4ac007'	System	02 May 2021 08:09:58
User entered 'No (N)'	System	02 May 2021 08:09:58

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-05-02T04:09:55-04:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '0e8934e1-656f-4bd9-9643-8c2a1e4ac007'	System	02 May 2021 08:09:58
User entered '02 May 2021 04:09:55'	System	02 May 2021 08:09:58

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:51:36

US3022276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:51:36
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:51:36

US3022276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:51:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:55:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-28T04:04:05-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '08d8999a-da95-4347-8c15-6951b7daff62'	System	28 Feb 2021 09:04:31
User entered 'No (N)'	System	28 Feb 2021 09:04:31

US3022276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:51:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:55:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5CDFAD75-61DC-4367-99C2-139964828121)', Time: '2021-02-28T04:04:08-05:00', User OID: 'PatientReportedOutcome (US3022276)', ODM File OID: '08d8999a-da95-4347-8c15-6951b7daff62' User entered '28 Feb 2021 09:04:08'	System	28 Feb 2021 09:04:31
	System	28 Feb 2021 09:04:31

US3022276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:16:48

US3022276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:16:48

US3022276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:16:48

US3022276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 16:16:48

US3022276

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:16:55

US3022276

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:46:04
User entered 'I'	(b) (4), (b) (6) System	03 Dec 2020 16:16:55

US3022276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 18:28:04

US3022276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '23 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 18:28:04

US3022276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Dec 2020 18:28:04

US3022276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:04

US3022276

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:14

US3022276

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User entered 'I'	System	23 Dec 2020 18:28:14

US3022276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:10

US3022276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:00:10

US3022276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:00:10

US3022276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:10

US3022276

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:00:14

US3022276

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User entered 'I'	System	20 Jan 2021 20:00:14

US3022276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 23:18:04

US3022276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:18:04

US3022276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Feb 2021 23:18:04

US3022276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:18:04

US3022276

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:17:54

US3022276

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:06:31
User entered 'I'	System	18 Feb 2021 23:17:54

US3022276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 20:31:41

US3022276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 20:31:41

US3022276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:31:41

US3022276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered 'VISIT4'	System	09 Mar 2021 20:31:41

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered empty.	System	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered empty.	System	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered empty.	System	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered empty.	System	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered empty.	System	30 Mar 2021 16:44:11

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05

US3022276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05

US3022276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:32:01

US3022276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 20:32:01

US3022276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:32:14

US3022276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:32:14

US3022276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered '14:42'	(b) (4), (b) (6)	09 Mar 2021 20:32:14

US3022276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered '09 Mar 2021 14:42'	System	09 Mar 2021 20:32:14

US3022276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:32:34

US3022276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:03:05
User entered 'I'	System	09 Mar 2021 20:32:34

US3022276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:58:30

US3022276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:20:49
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:58:30

US3022276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:58:30

US3022276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:58:30

US3022276

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:58:33

US3022276

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:58:33

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:37

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:37

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:37

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 18:19:37

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:23:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:31:50

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:58:14
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:23:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 12:23:29
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:28:45
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:31:50

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User entered empty.	System	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User entered empty.	System	01 Feb 2021 18:19:49

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:20:17

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:20:17

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '10:34'	(b) (4), (b) (6)	01 Feb 2021 18:20:17

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User entered '01 Feb 2021 10:34'	System	01 Feb 2021 18:20:17

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:22:10

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:22:10

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '10:59'	(b) (4), (b) (6)	01 Feb 2021 18:22:10

US3022276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:35
User entered '01 Feb 2021 10:59'	System	01 Feb 2021 18:22:10

US3022276

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:51:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 208 (16MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:30:30
Query 'Per DM CLR: Per Safety Follow Up Diary Day 208 (16MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'no ae needed, in medical history ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:47:50
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 208 (16MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:00:41
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:54:52

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:19:28
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
DataPoint activated with code reason code Data required.	(b) (4)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:26
User entered	System	09 Oct 2020 16:43:17
'USA-US051-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	09 Oct 2020 16:43:17

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:19:31
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'PV Query: As the surgery was pre-planned prior to onset of study, please consider deleting event from the EDC. If not, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:03:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Back injury, LLT: Back injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:14:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:14:59
Data point term sent to Coder	System	07 Dec 2020 18:13:50
Query 'PV Query: As the surgery was pre-planned prior to onset of study, please consider deleting event from the EDC. If not, please clarify.' answered with 'It was pre planned but subject stayed overnight and per pi he wanted it to stay as ae/sae' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 18:13:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
Data point term sent to Coder	System	03 Dec 2020 16:16:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User opened query 'PV Query: As the surgery was pre-planned prior to onset of study, please consider deleting event from the EDC. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:43:00
User closed query 'PV Query: It was reported that the subject was diagnosed with a synovial cyst in Sep 2020. Please consider updating the event term to the final diagnosis (reason for the back surgery). Else clarify.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:57:19
Query 'PV Query: It was reported that the subject was diagnosed with a synovial cyst in Sep 2020. Please consider updating the event term to the final diagnosis (reason for the back surgery). Else clarify.' answered with 'This term is correct.' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:51:30

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject was diagnosed with a synovial cyst in Sep 2020. Please consider updating the event term to the final diagnosis (reason for the back surgery). Else clarify.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:16:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Back injury, LLT: Back injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:35:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:35:27
Data point term sent to Coder	System	09 Oct 2020 12:30:47
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 12:29:55
User entered 'Worsening of back injury' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 12:29:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:57:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:57:35
Data point term sent to Coder	System	09 Oct 2020 11:56:28
User entered 'Back Pain'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:19:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:19:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:03
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User closed query 'PV Query: Please update the event start date to when the symptom of worsening back pain occurred' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:57:27
Query 'PV Query: Please update the event start date to when the symptom of worsening back pain occurred' answered with 'This date is correct' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:51:08
User opened query 'PV Query: Please update the event start date to when the symptom of worsening back pain occurred' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:15:39
User entered '02 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	System	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:21:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User closed query 'PV Query: Please confirm the event resolution date. EDC has 02 Oct 2020 as the event end date, whereas the paper SAE form has 03 Oct 2020 as the event resolution date. Please confirm and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:17:43
Query 'PV Query: Please confirm the event resolution date. EDC has 02 Oct 2020 as the event end date, whereas the paper SAE form has 03 Oct 2020 as the event resolution date. Please confirm and update accordingly.' answered with 'update' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:40:28
User entered '03 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:40:23
User opened query 'PV Query: Please confirm the event resolution date. EDC has 02 Oct 2020 as the event end date, whereas the paper SAE form has 03 Oct 2020 as the event resolution date. Please confirm and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:16:21
User entered '02 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	System	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	09 Oct 2020 13:41:03
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'I'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '03 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:57:38
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'Updated' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:52:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:52:25
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:16:42
User entered 'None (NONE)'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:56:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'I'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'I'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:56:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:26:36
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User closed query 'PV Query: Please confirm if the surgery was preplanned prior to the start of the study drug.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:57:44
User closed query 'PV Query: Was the subject tested for COVID-19, while hospitalized? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:57:42
Query 'PV Query: Please confirm if the surgery was preplanned prior to the start of the study drug.' answered with 'Yes that is correct' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:52:02
Query 'PV Query: Was the subject tested for COVID-19, while hospitalized? If yes, please provide results.' answered with 'No' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:51:42
User opened query 'PV Query: Please confirm if the surgery was preplanned prior to the start of the study drug.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:15:52
User opened query 'PV Query: Was the subject tested for COVID-19, while hospitalized? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:15:15
User closed query 'PV Query: As the surgery was pre-planned, please clarify whether the event was a treatment emergent AE.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:18:25
Query 'PV Query: As the surgery was pre-planned, please clarify whether the event was a treatment emergent AE.' answered with 'Yes' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:40:36
User opened query 'PV Query: As the surgery was pre-planned, please clarify whether the event was a treatment emergent AE.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:14:27
User entered 'SUBJECT WENT TO THE HOSPITAL FOR A PRE-PLANNED SURGERY' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 13:41:40
User entered 'Subject went in to the hospital for a pre-planned surgery' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 12:29:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject had back surgery due to back pain'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'I'	System	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered 'I'	System	09 Oct 2020 11:56:23

US3022276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Dec 2020 18:13:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:16:28
User entered '0'	System	09 Oct 2020 11:56:23

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:30

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:48:28
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:19
User closed query 'Per CDM, DM CLR re-query: Response is noted; however there are no medications with an indication Pain at Injection site for 25 Sep 2020 (Diary Dose 2, Day 2) and Headache for 30 Sep 2020 (Diary Dose 2, Day 7). Review and update as appropriate, else confirm data is correct as entered. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:25:52
Query 'Per CDM, DM CLR re-query: Response is noted; however there are no medications with an indication Pain at Injection site for 25 Sep 2020 (Diary Dose 2, Day 2) and Headache for 30 Sep 2020 (Diary Dose 2, Day 7). Review and update as appropriate, else confirm data is correct as entered. Thank you. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:05:18
User opened query 'Per CDM, DM CLR re-query: Response is noted; however there are no medications with an indication Pain at Injection site for 25 Sep 2020 (Diary Dose 2, Day 2) and Headache for 30 Sep 2020 (Diary Dose 2, Day 7). Review and update as appropriate, else confirm data is correct as entered. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:55:25
Query 'Per CDM, DM CLR re-query: Response is noted; however there are no medications with an indication Pain at Injection site for 25 Sep (Diary Dose 2, Day 2) and Headache (Diary Dose 2, Day 7). Review and update as appropriate, else re-clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:54:35
User opened query 'Per CDM, DM CLR re-query: Response is noted; however there are no medications with an indication Pain at Injection site for 25 Sep (Diary Dose 2, Day 2) and Headache (Diary Dose 2, Day 7). Review and update as appropriate, else re-clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:54:22

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:30

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR re-query: Please note that there is no medication with an Indication Pain at Injection site for 25 Sep (Diary Dose 2, Day 2). Please also note that in response to the previous query the indication of CM#20 has been updated from Headache to Pain at Injection site, yet per Diary Dose 2, medication was taken for Headache on both 25 Sep and 30 Sep. Review and update the Con Med page as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:54:22
Query 'Per CDM, DM CLR re-query: Please note that there is no medication with an Indication Pain at Injection site for 25 Sep (Diary Dose 2, Day 2). Please also note that in response to the previous query the indication of CM#20 has been updated from Headache to Pain at Injection site, yet per Diary Dose 2, medication was taken for Headache on both 25 Sep and 30 Sep. Review and update the Con Med page as appropriate, else clarify. ' answered with 'they are already listed' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:50:18
User opened query 'Per CDM, DM CLR re-query: Please note that there is no medication with an Indication Pain at Injection site for 25 Sep (Diary Dose 2, Day 2). Please also note that in response to the previous query the indication of CM#20 has been updated from Headache to Pain at Injection site, yet per Diary Dose 2, medication was taken for Headache on both 25 Sep and 30 Sep. Review and update the Con Med page as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:23:31
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:23:31

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:30

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:06:40
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 05:29:02
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:03:15

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 23:04:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:04:22
Data point term sent to Coder	System	21 Aug 2020 23:04:09
User entered 'EMPAGLIFLOZIN'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:03:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:03
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'DIABETES'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:03:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '25'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:10
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2005'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:03:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:03:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:03:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:03:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:23
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: ESTREN DERIVATIVES, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: NORETHINDRONE [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:47:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:47:04
Data point term sent to Coder	System	22 Oct 2020 15:41:57
Coding entries removed.	Shanice Bennett (b) (4)	22 Oct 2020 15:41:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: NORETHINDRONE [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 11:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 11:50:43
Data point term sent to Coder	System	21 Aug 2020 23:05:11
User entered 'NORETHINPROLE'	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:26
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CMD: Please change the indication term "Hormone Replacement" to "Endometriosis" if Endometriosis is the indication for this medication or explain/reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:25:25
Query 'Per CMD: Please change the indication term "Hormone Replacement" to "Endometriosis" if Endometriosis is the indication for this medication or explain/reconcile. Thank you. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:41:12
User entered 'Endometriosis' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:41:08
User opened query 'Per CMD: Please change the indication term "Hormone Replacement" to "Endometriosis" if Endometriosis is the indication for this medication or explain/reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:21:43
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:17:27
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 and Update eCRF as appropriate. ' answered with 'updated - endometriosis ' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:26:38
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:28:51
User entered 'HORMONE REPLACEMENT'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:01
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '5'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:05
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'once daily (QD)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:10
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:15
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2015'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User closed query 'Per source end date for this medication is 31Aug2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:40:58
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source end date for this medication is 31Aug2020. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:20:22
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:19:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:19:51
User opened query 'Per source end date for this medication is 31Aug2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:39:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:30
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:38:18
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:19:51
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:19:51
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:16
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User entered '1'	System	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User entered '1'	System	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:47
User entered '804 (804)'	System	21 Aug 2020 23:04:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:43:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:43:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	12 Apr 2021 19:21:39 12 Apr 2021 19:20:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:31:57
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 04:17:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 04:17:27
Data point term sent to Coder	System	21 Aug 2020 23:06:13
User entered 'VARENICLINE'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:32:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Indication is listed as Smoking sensation and the drug is used to stop spoking. Please review and consider changing to cessation instead.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:41:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Indication is listed as Smoking sensation and the drug is used to stop spoking. Please review and consider changing to cessation instead.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:21:04
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:20:51
User entered 'SMOKING CESSATION' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:20:51
User opened query 'Indication is listed as Smoking sensation and the drug is used to stop spoking. Please review and consider changing to cessation instead.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:31:23
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'SMOKING SENSATION'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:32:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'I'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:32:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:33:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:33:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:33:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2018'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:33:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:33:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 23:05:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:05:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:05:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: OLOPATADINE HYDROCHLORIDE, PRODUCTSYNONYM: OLOPATADINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 06:03:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 06:03:22
Data point term sent to Coder	System	21 Aug 2020 23:06:13
User entered 'OLOPATADINE HCL'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:14
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'ALLERGIC CONJUNCTIVITIS'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0.1'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Other (OTHER)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'DROP'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:22:25
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'this is correct. subject takes these as eye drops. ' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:27:32
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:31:07
User entered 'Intraocular (INTRAOCULAR)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:58
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2019'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:05:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:05:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR re-query: Response noted. However, symbicort is a combination drug. Please review medication name or the dose. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 08:42:12
Query 'Per DM CLR re-query: Response noted. However, symbicort is a combination drug. Please review medication name or the dose. Update as appropriate. ' answered with 'This information is correct.' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:43:59
User opened query 'Per DM CLR re-query: Response noted. However, symbicort is a combination drug. Please review medication name or the dose. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:54:59
User closed query 'Per DM CLR: Please review this medication and confirm if this a combination product. If yes, please update the medication name to record both components or record the trade/brand name, and ensure that doses of both components is recorded in the dose field. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:24:38
Query 'Per DM CLR: Please review this medication and confirm if this a combination product. If yes, please update the medication name to record both components or record the trade/brand name, and ensure that doses of both components is recorded in the dose field. Update as appropriate, otherwise clarify.' answered with 'updated subject stated she takes symbicort and it is 4.5 mcg.' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:26:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:21:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:21:52
Data point term sent to Coder	System	01 Oct 2020 18:19:21
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:19:02
User entered 'symbicort' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:19:02
User opened query 'Per DM CLR: Please review this medication and confirm if this a combination product. If yes, please update the medication name to record both components or record the trade/brand name, and ensure that doses of both components is recorded in the dose field. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	10 Sep 2020 10:32:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOID, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:08:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:08:25
Data point term sent to Coder	System	21 Aug 2020 23:07:14
User entered 'BUDESONIDE'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:06:33

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'ASTHMA'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '4.5'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:42:14
Query 'Per CDM: ug is an option for dose units please reconcile.' answered with 'updatedd' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:48:49
User entered 'ug (ug)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:48:43
User opened query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:18:16
User entered 'Other (OTHER)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:06:33

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 11:48:43
	(b) (4)	
User entered 'MCG'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 1992'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:06:33
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 23:06:33

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:06:33

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:06:33

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:34
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 20:38:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:38:02
Data point term sent to Coder	System	01 Oct 2020 18:21:26
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:21:01
User entered 'Cyanocobalamin' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:21:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:05:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:05:40
Data point term sent to Coder	System	21 Aug 2020 23:08:15
User entered 'CYANOCOBA;A,OM'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'VITAMIN B-12 DEFICIENCY'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 14:39:29
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'upadted' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:28:15
User entered '1000' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:28:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:34:52
User entered '1.000'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:48
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:42:46
Query 'Per CDM: ug is an option for dose units please reconcile.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:49:07
User entered 'ug (ug)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:49:02
User opened query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:16:17
User entered 'Other (OTHER)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 11:49:02
	(b) (4)	
User entered 'MCG'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'every month (QM)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:52:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source Med History and Con Med log list start date as 20218. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:42:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source Med History and Con Med log list start date as 20218. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:22:35
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:22:18
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:22:18
User opened query 'Per source Med History and Con Med log list start date as 20218. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:58:03
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:27:39
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:33:04
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 18:33:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:35:30
User entered 'UN UNK 2018'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:58:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:58:31
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:58:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:58:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:29
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	21 Aug 2020 23:07:29

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:58:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:09:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:09:26
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 23:08:16
User entered 'GLIPIZIDE'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'DIABETES'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:07
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '10'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:07:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2005'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:07:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:07:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:07:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:07:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 23:10:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:10:27
Data point term sent to Coder	System	21 Aug 2020 23:09:16
User entered 'METFORMIN'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:08:23

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'DIABETES'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:59:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '500'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:00:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:00:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:00:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2005'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:23
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:08:23

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:08:23

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:08:23

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Aug 2020 13:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 13:31:42
Data point term sent to Coder	System	21 Aug 2020 23:09:16
User entered 'ASPART INSULIN'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'DIABETES'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '100'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:43
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: IU is an option for dose units please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:59:53
Query 'Per CDM: IU is an option for dose units please reconcile.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:49:26
User entered 'IU (IU)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:49:21
User opened query 'Per CDM: IU is an option for dose units please reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:14:42
User entered 'Other (OTHER)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:02:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 11:49:21
	(b) (4)	
User entered 'UNIT'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per source this is taken once daily. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:42:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source this is taken once daily. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:55:15
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:54:57
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:54:57
User opened query 'Per source this is taken once daily. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:03:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:03:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:04:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:15:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:22:20
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:36:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:04:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source Med History and Con Med log list start date as 2005. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:43:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source Med History and Con Med log list start date as 2005. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:55:32
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:54:57
User entered 'UN UNK 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:54:57
User opened query 'Per source Med History and Con Med log list start date as 2005. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:05:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2004' reason for change: Data Entry Error	Stella Yoon (b) (4)	01 Oct 2020 18:22:16
User entered 'UN UNK 2005'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:08:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 20:54:57
User entered '2'	System	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:08:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:11:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:11:28
Data point term sent to Coder	System	21 Aug 2020 23:10:19
User entered 'ROSUVASTATIN'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:18
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:23
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'HYPERLIPIDEMIA'	(b) (4) Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:30
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '5'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:32
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:38
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:41
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:43
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:50
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:52
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
	(b) (4), (b) (6)	
User closed query 'Per source end date was updated to 31Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:44:38
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
	(b) (4)	
Query 'Per source end date was updated to 31Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:56:33
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:56:09
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:56:09
	(b) (4), (b) (6)	
User opened query 'Per source end date was updated to 31Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:08:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:56:09
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:56:09
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:52
User entered '804 (804)'	(b) (4), (b) (6) System	21 Aug 2020 23:09:44

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:34:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:34:56
Data point term sent to Coder	System	01 Oct 2020 18:33:57
Coding entries removed.	Stella Yoon (b) (4)	01 Oct 2020 18:33:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:01:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:01:11
Data point term sent to Coder	System	21 Aug 2020 23:11:20
User entered 'ESTRADIOL PATCH'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:53
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:09:40
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR re-query: Response noted. However, no condition is recorded. Please update to include medical condition. Reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:20:52
Query 'Per DM CLR re-query: Response noted. However, no condition is recorded. Please update to include medical condition. Reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'There is not a medical condition it is taken for a replacement due to hormones.' (Site from DM).	Morgan Deal (b) (4)	13 Nov 2020 20:45:14
User opened query 'Per DM CLR re-query: Response noted. However, no condition is recorded. Please update to include medical condition. Reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:45:29
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:15:00
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 and Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:33:16
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:38:59

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User entered 'HORMONE REPLACEMENT'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:09:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0.05'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:09:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:09:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:01
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'other (OTHER)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:03
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'TWICE A WEEK'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Transdermal (TRANSDERMAL)'	Stella Yoon (b) (4)	01 Oct 2020 18:33:31
reason for change: Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:28
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review route to record the actual route of administration of this medication instead of the dosage form (e.g Transdermal, Oral, Topical, etc.). Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review route to record the actual route of administration of this medication instead of the dosage form (e.g Transdermal, Oral, Topical, etc.). Update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:12:14
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	01 Oct 2020 18:33:35
	(b) (4)	
User opened query 'Per DM CLR: Please review route to record the actual route of administration of this medication instead of the dosage form (e.g Transdermal, Oral, Topical, etc.). Update as appropriate, otherwise clarify.' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:33:31
User entered 'PATCH'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 10:39:30
	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:34
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
User closed query 'Per source end date is 31Aug20. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:43:52
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source end date is 31Aug20. Please verify and update as needed.' answered with 'updatedx' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:57:39
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:57:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:57:23
User opened query 'Per source end date is 31Aug20. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:11:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:57:23
	(b) (4), (b) (6)	
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:57:23
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:03
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 23:10:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Aug 2020 11:50:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:50:35
Data point term sent to Coder	System	21 Aug 2020 23:11:20
User entered 'MONTELUKAST'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:11:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'SEASONAL ALLERGIES'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:11:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '10'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:11:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:16
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:11:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:11:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:11:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 23:13:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:13:29
Data point term sent to Coder	System	21 Aug 2020 23:12:21
User entered 'OMEPRAZOLE'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:31
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '40'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:12:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2003'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:11:54
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:11:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:20
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 23:14:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:14:30
Data point term sent to Coder	System	21 Aug 2020 23:13:23
User entered 'FEXOFENADINE'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:12:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:26
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'SEASONAL ALLERGIES'	(b) (4) Chevon Roberts (b) (4)	21 Aug 2020 23:12:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '180'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2019'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:13:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:14:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:24
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:12:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:12:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:12:24

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
User closed query 'Per source name is Escitalopram Oxalate. Please update to match source document.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:45:01
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:24:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:24:40
Data point term sent to Coder	System	12 Apr 2021 20:59:26
Query 'Per source name is Escitalopram Oxalate. Please update to match source document.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:59:05
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 20:58:46
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:58:46
User entered 'ESCITALOPRAM oxalate' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:58:46
User opened query 'Per source name is Escitalopram Oxalate. Please update to match source document.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:16:29
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:14:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:14:30
Data point term sent to Coder	System	21 Aug 2020 23:13:23
User entered 'ESCITALOPRAM'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:34
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'ANXIETY'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:44
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '20'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:50
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:52
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'once daily (QD)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:54
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:57
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:16:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:07
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
User closed query 'Per source end date was updated to 20Sep2020. Please verify and update to match source.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:47:10
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source end date was updated to 20Sep2020. Please verify and update to match source.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:59:20
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:58:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:58:46
User opened query 'Per source end date was updated to 20Sep2020. Please verify and update to match source.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:17:43
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:58:46
	(b) (4), (b) (6)	
User entered '20 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:58:46
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:16:01
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 18:33:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 18:33:44
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:41:26
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:07
User entered '804 (804)'	(b) (4), (b) (6) System	21 Aug 2020 23:12:58

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 04:30:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 04:30:30
Data point term sent to Coder	System	21 Aug 2020 23:14:24
User entered 'TOPIRAMATE'	Chevon Roberts (b) (4) (b) (4)	21 Aug 2020 23:13:27

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:10
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'BIPOLAR'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '25'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'UN UNK 2015'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	21 Aug 2020 23:13:27
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 23:13:27

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 23:13:27

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 23:13:27

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 15:37:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 15:37:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:22:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:22:05
Data point term sent to Coder	System	01 Oct 2020 18:20:25
User entered 'Albuterol'	Stella Yoon (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'asthma'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '8'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 10:19:07
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:46:16
User entered 'ug (ug)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:46:09
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:46:04
User entered 'g (g)'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'as needed (PRN)'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 10:31:52
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify' answered with 'This date is correct ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 20:23:55
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:25:42
User entered 'un UNK 1988'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:20:10

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
User closed query 'Per source this is listed as Acetaminophen. Please update to match source documentation.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:47:31
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:24:42
Data point term sent to Coder	System	12 Apr 2021 21:00:27
Query 'Per source this is listed as Acetaminophen. Please update to match source documentation.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:00:25
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 21:00:07
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 21:00:07
User entered 'acetaminophen' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 21:00:07
User opened query 'Per source this is listed as Acetaminophen. Please update to match source documentation.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:23:15
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:33:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:33:01
Data point term sent to Coder	System	01 Oct 2020 18:31:54

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Tylenol Extra Strength'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:18
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:21
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:36:00
Query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' answered with 'no ae ' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:56:18
User opened query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:21:01

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:19:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'It was during diary entry.' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:46:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:46:27

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:25
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '500'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:30
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:33
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'once (ONCE)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:38
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:40
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 18:32:18
User entered '23 Aug 2020' reason for change: Data Entry Error	Stella Yoon (b) (4)	01 Oct 2020 18:32:18
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 18:31:16
User entered empty.	System	01 Oct 2020 18:31:16
	Stella Yoon (b) (4)	01 Oct 2020 18:31:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:50
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:52
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 18:32:18
User entered '23 Aug 2020' reason for change: Data Entry Error	Stella Yoon (b) (4)	01 Oct 2020 18:32:18
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 18:31:16
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:23:56
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Stella Yoon (b) (4)	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:45
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 18:31:16

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 23:21:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Mar 2021 23:21:06
Data point term sent to Coder	System	01 Mar 2021 19:05:14
Coding entries removed.	(b) (4), (b) (6)	01 Mar 2021 19:04:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:34:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	01 Oct 2020 18:34:15
Data point term sent to Coder	System	01 Oct 2020 18:32:56
User entered 'Advil'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES & PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES & PAIN AT INJECTION SITE did not meet the AE reporting criteria.	(b) (4), (b) (6)	12 Mar 2021 01:09:52
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES & PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES & PAIN AT INJECTION SITE did not meet the AE reporting criteria.	(b) (4), (b) (6)	10 Mar 2021 17:20:12
' answered with 'no ae needed' (Site from DM).		

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES & PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES & PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	09 Mar 2021 07:06:20
Signature has been broken.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 23:02:19
User entered 'HEADACHES & pain at injection site' reason for change: Data Entry Error User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	01 Mar 2021 19:04:35 01 Mar 2021 19:04:35 24 Feb 2021 00:34:01
User closed query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM). Query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' answered with 'no ae' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	23 Nov 2020 14:36:07 19 Nov 2020 21:56:26

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:21:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:21:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'It was during diary entry. No AE' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:47:04

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:47:43
User entered 'headaches'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:18
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '200'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:21
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:23
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
	(b) (4), (b) (6)	
User closed query 'Per source this was taken BID. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:47:59
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
	(b) (4)	
Query 'Per source this was taken BID. Please verify and update as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:01:54
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 21:01:21
	(b) (4), (b) (6)	
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 21:01:21
User opened query 'Per source this was taken BID. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:26:01
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'once (ONCE)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:07
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:14
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:17
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '25 Sep 2020'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:23
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:26
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:34
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '25 Sep 2020'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:38
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	Stella Yoon (b) (4)	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
User entered '2'	(b) (4), (b) (6)	
	System	12 Apr 2021 21:01:21
User entered empty.	System	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
User entered '1'	(b) (4), (b) (6)	
	System	12 Apr 2021 21:01:21
User entered empty.	System	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:03:49
User entered '804 (804)'	(b) (4), (b) (6)	
	System	12 Apr 2021 21:01:21
User entered empty.	System	01 Oct 2020 18:32:43

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 19:05:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 19:05:54
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Mar 2021 19:05:14 01 Mar 2021 19:04:53
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 14:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 14:07:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Feb 2021 14:07:32 05 Feb 2021 14:06:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:21:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:21:01
Data point term sent to Coder	System	01 Oct 2020 19:20:29
User entered 'ADVIL'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:52
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:26:54
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:19
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 19:04:53
User entered 'HEADACHE' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:04:53
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'pain at injection site' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 14:06:32
User closed query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:36:15
Query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' answered with 'no ae' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:56:35
User opened query 'Per CDM, per DM CLR re-query: Please note that solicited adverse reactions reported in diary need to be recorded on the AE page but ONLY if they meet the are reporting criteria as per protocol section 8.3.4. If the event meets the criteria, add an entry to the AE page, else confirm in a query response that it does not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:21:27

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:21:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'During diary entry. No AE' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:47:19
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:48:01

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:01
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '200'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:04
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:11
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:14
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:17
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:19
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:22
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:24
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:28
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:31
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:27:35
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
User entered '2'	System	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
User entered '1'	System	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:05
User entered '804 (804)'	System	01 Oct 2020 19:19:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:30
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 11:52:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 11:52:25
Data point term sent to Coder	System	09 Oct 2020 11:51:24
User entered 'Flu Vaccine'	Shanice Bennett (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:32
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:34
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'flu vaccine'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0.5'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:50
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:52
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'once (ONCE)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:54
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:57
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:28:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:03
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '03 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:09
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:11
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '03 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:14
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
User entered empty.	System	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
User entered empty.	System	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:10
User entered empty.	System	09 Oct 2020 11:50:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 13:35:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:35:23
Data point term sent to Coder Coding entries removed.	System Shanice Bennett (b) (4)	09 Oct 2020 12:31:48 09 Oct 2020 12:31:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 11:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:53:20
Data point term sent to Coder User entered 'oxycodone'	System Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:52:25 09 Oct 2020 11:51:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Worsening of back injury' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 12:31:03
	(b) (4)	
User entered 'back pain'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '5'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:48
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'as needed (PRN)'	(b) (4) Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:29:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:30:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:30:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source medication is ongoing. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:48:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source medication is ongoing. Please verify and update as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:53:37
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:53:17
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:53:17
User opened query 'Per source medication is ongoing. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 14:30:20
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:30:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:15:07
Query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:57:08
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	19 Nov 2020 21:57:01
User opened query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:13:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:12:19
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:12:17

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'Date is not required if it is not ongoing.' (Site from System).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:48:27
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.'	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:48:08
' answered with 'Updated' (Site from DM).		
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:47:58
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:47:58
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.'	(b) (4), (b) (6) (b) (4)	02 Nov 2020 08:48:43
' (Site from DM).		
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:51:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:53:17
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:53:17
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Nov 2020 20:47:58
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Nov 2020 20:47:47
User entered '3 Oct 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 20:47:47
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:30:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:51:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:51:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:51:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:51:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 13:26:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:26:31
Data point term sent to Coder Coding entries removed.	System Shanice Bennett (b) (4)	09 Oct 2020 12:31:48 09 Oct 2020 12:31:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 11:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:53:20
Data point term sent to Coder User entered 'Celecoxib'	System Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:52:26 09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:15
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Worsening of back injury' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 12:31:18
	(b) (4)	
User entered 'back pain'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:19
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '200'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:21
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4)	09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:23
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:31:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:48:47
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source this is ongoing. Please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:52:36
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:52:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:52:11
User opened query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:32:14
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:15:18
Query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:57:26
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	19 Nov 2020 21:57:20
User opened query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:14:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:13:58
Query 'Data is required. Please complete.' answered with 'Date is not required if it not ongoing' (Site from System).	Morgan Deal (b) (4)	13 Nov 2020 20:49:09

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Updated' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:48:47
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:48:47
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:49:09
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:52:11
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:52:11
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '3 Oct 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 20:48:47
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:32:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:12
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 11:52:12

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:32:36
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 13:33:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:33:27
Data point term sent to Coder Coding entries removed.	System Shanice Bennett (b) (4)	09 Oct 2020 12:31:49 09 Oct 2020 12:31:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 11:54:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:54:19
Data point term sent to Coder User entered 'Methocarbamol'	System Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:53:27 09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:32:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 11:53:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 11:53:58
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 11:53:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 11:52:52
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:34:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Worsening of back injury' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 12:31:47
	(b) (4)	
User entered 'Back Pain'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:34:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '500'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:34:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per source frequency is listed as TID. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:49:17
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source frequency is listed as TID. Please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:51:08
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User opened query 'Per source frequency is listed as TID. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:34:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:28
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:49:33
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source this is ongoing. Please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:51:31
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User opened query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:36:17
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:14:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Updated' (Site from DM).	Morgan Deal (b) (4)	13 Nov 2020 20:49:47
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	13 Nov 2020 20:49:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:49:35
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:50:48
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '3 Oct 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 20:49:40
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:52:52
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 20:50:48
User entered '2'	System	09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 11:52:52

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:34
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 12:34:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 12:34:26
Data point term sent to Coder Coding entries removed.	System Shanice Bennett (b) (4)	09 Oct 2020 12:32:49 09 Oct 2020 12:32:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 11:55:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 11:55:21
Data point term sent to Coder User entered 'acetaminophen'	System Shanice Bennett (b) (4)	09 Oct 2020 11:54:27 09 Oct 2020 11:53:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Worsening of back injury' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Oct 2020 12:32:02
	(b) (4)	
User entered 'back pain'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '500'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:36:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:37:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:39:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:46:25
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source this is ongoing. Please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:49:57
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:49:32
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:49:32
User opened query 'Per source this is ongoing. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:39:30
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User closed query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:15:28
Query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:57:49
User entered 'No (N)' reason for change: Per Query Resolution	Shanice Bennett (b) (4)	19 Nov 2020 21:57:44
User opened query 'Per CDM: If the medication is no longer taken then "Ongoing?" should be marked as "No". The field should not remain empty. Kindy update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:14:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:14:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:14:15
Query 'Data is required. Please complete.' answered with 'Not required if it is not ongoing' (Site from System).	Morgan Deal (b) (4)	13 Nov 2020 20:50:25

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:50:09
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:50:04
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 20:50:04
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:49:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 11:53:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:49:32
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	12 Apr 2021 20:49:32
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '3 Oct 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	13 Nov 2020 20:50:04
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:39:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Oct 2020 11:53:32
	(b) (4)	

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:53:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:53:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:53:32

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:40:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:07
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:07
	(b) (4)	
Data point term sent to Coder	System	01 Apr 2021 15:45:16
User entered 'Trimethoprim / Sulfamethoxazole'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
Query 'Per source this is used to prevent infection. Please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:48:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:48:02
User opened query 'Per source this is used to prevent infection. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:40:45
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 14:40:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:40:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:40:50
User entered 'antibiotic/ prevent infection'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:40:56
User entered '80/400'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:40:58
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:01
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:03
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:06
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:24
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:26
User entered '20 Oct 2020'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:28
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:33
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:45:00

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 15:47:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 15:47:56
Data point term sent to Coder	System	01 Apr 2021 15:46:17
User entered 'buspirone'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:55
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:41:58
User entered 'anxiety'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:02
User entered '10'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:05
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:07
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:10
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:13
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:17
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:19
User entered '02 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:22
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:25
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:28
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:45:49

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:19:32
Data point term sent to Coder	System	01 Apr 2021 15:47:17
User entered 'spironolactone'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:35
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:37
User entered 'post menopausal'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:43
User entered '50'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:47
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:50
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:56
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:42:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:02
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:06
User entered '12 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:10
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:18
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:23:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:43:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:51:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:46:50

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:51:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:46:02
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	09 Oct 2020 12:30:19

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:46:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered '02 Oct 2020'	Shanice Bennett (b) (4)	09 Oct 2020 12:30:33
	(b) (4)	

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:47:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Back Surgery'	Shanice Bennett (b) (4)	09 Oct 2020 12:30:33
	(b) (4)	

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	09 Oct 2020 12:30:33
	(b) (4)	

US3022276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:30

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:47:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Oct 2020 12:30:33
	(b) (4)	

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered	System	09 Oct 2020 16:43:17
'USA-US051-2020-MRNA-1273-P301000006'		

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Paul'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Bradley'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '340 Eisenhower Dr.'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Savannah'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'GA'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '31406'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:18:43
User entered 'US'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '3'	(b) (4)	16 Nov 2020 22:58:57
User entered '2'	System	23 Oct 2020 16:18:54
User entered '1'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered	System	09 Oct 2020 16:43:17
'USA-US051-2020-MRNA-1273-P301000006'		

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Paul'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Bradley'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '340 Eisenhower Dr.'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Savannah'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'GA'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '31406'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:18:43
User entered 'US'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '3'	(b) (4)	16 Nov 2020 22:58:57
User entered '2'	System	23 Oct 2020 16:18:54
User entered '1'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '09/Oct/2020 16:43'	(b) (4) System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 16:18:43
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered	System	09 Oct 2020 16:43:17
'USA-US051-2020-MRNA-1273-P301000006'		

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Paul'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Bradley'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '340 Eisenhower Dr.'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Savannah'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'GA'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '31406'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:18:43
User entered 'US'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '3'	(b) (4)	16 Nov 2020 22:58:57
User entered '2'	System	23 Oct 2020 16:18:54
User entered '1'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '23/Oct/2020 16:18'	(b) (4) System	23 Oct 2020 16:18:54

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 16:18:57
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 16:18:54

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered	System	09 Oct 2020 16:43:17
'USA-US051-2020-MRNA-1273-P301000006'		

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:48
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:16:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:34:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Yes (Y)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'No (N)'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Paul'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:18
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Bradley'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '340 Eisenhower Dr.'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'Savannah'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered 'GA'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:17:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 16:43:41
User entered '31406'	System	09 Oct 2020 16:43:17

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:18:43
User entered 'US'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '3'	(b) (4)	16 Nov 2020 22:58:57
User entered '2'	System	23 Oct 2020 16:18:54
User entered '1'	System	09 Oct 2020 16:43:48

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered '16/Nov/2020 22:58'	(b) (4) System	16 Nov 2020 22:58:57

US3022276

Folder: SAE USA-US051-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:34:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:58:57