

US3052044 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:55:29

All time stamps listed in this document are displayed in GMT

US3052044

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

[Participant ID](#)

US3052044

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

US3052044

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3052044

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	True
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3052044

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 07:59:05

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Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

US3052044

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3052044

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	CABG SURGERY
Start date (dd MMM yyyy)	05 APR 2009
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)	05 APR 2009
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	APR 2009
Stop Year (derived)	2009

US3052044

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	STENT PLACEMENT - HEART
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 (5)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	MELANOMA - MIDDLE TOE ON RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3052044

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	MELANOMA - LEFT CHEST
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	DIABETES WITH INSULIN PUMP
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: Medical History (9)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	DUPUTRYEN'S DISEASE SURGERY - BOTH HANDS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	COPD DUE TO ASBESTOS EXPOSURE
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	CARDIAC BLOOD VESSEL STRICTURE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	MELANOMA REMOVAL SURGERY - MIDDLE TOE RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3052044

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	MELANOMA REMOVAL SURGERY - LEFT CHEST
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	ROTATOR CUFF SURGERY - LEFT SHOULDER
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	ROTATOR CUFF INJURY - RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3052044

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 JUL 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 10:59
Height (xxx.x)	69 in
Weight (xxx.x)	214 lb
BMI (xxx.x)	31.66835 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)	

US3052044

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3052044

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

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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	False
Specify	

US3052044

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 142456

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Height	ND - Not Done
Weight	ND - Not Done

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 10:59
Temperature (xxx.x)	98.6 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 12:32
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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) 31 JUL 2020

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

Treatment Date and Time (derived) 31 JUL 2020 11:59

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) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	11:51 (24 HR)
Collection date and time (derived)	31 JUL 2020 11:51

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:27	31 JUL 2020 11:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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 14:55:29

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

98.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 31 JUL 2020 12:34

PC Open Date & Time 31 JUL 2020 12:19

PC Close Date & Time 31 JUL 2020 14:49

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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 98.0 °F

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

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

PC Time Stamp	31 JUL 2020 19:41
PC Open Date & Time	31 JUL 2020 15:44
PC Close Date & Time	01 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

97.8 °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

01 AUG 2020 21:32

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 21:34

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 20:13

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:07

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 AUG 2020 09:35

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

98.4 °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

07 AUG 2020 00:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 12:33

PC Open Date & Time

31 JUL 2020 12:19

PC Close Date & Time

31 JUL 2020 14:49

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

31 JUL 2020 19:43

PC Open Date & Time

31 JUL 2020 15:44

PC Close Date & Time

01 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

01 AUG 2020 21:32

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

02 AUG 2020 21:35

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

03 AUG 2020 20:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

04 AUG 2020 20:07

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 09:36

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 00:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 12:34
PC Open Date & Time	31 JUL 2020 12:19
PC Close Date & Time	31 JUL 2020 14:49

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 19:44
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PC Open Date & Time	31 JUL 2020 15:44
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PC Close Date & Time	01 AUG 2020 11:59
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US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

61 of 2423

EAB) (1725)

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:33
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

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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US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 21:36
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

65 of 2423

EAB) (1725)

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 20:14
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

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)

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:08
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 09:37
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

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 ☒

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

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	08 AUG 2020 10:00
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3052044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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 _____

US3052044

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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

Visit date (dd MMM yyyy)	26 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	VISIT2
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US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 11:42 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:42

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

US3052044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	11:28 (24 HR)
Collection date and time (derived)	26 AUG 2020 11:28

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	26 AUG 2020 11:32
Nasopharyngeal Swab 2	No		

US3052044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

98.4 °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

26 AUG 2020 12:23

PC Open Date & Time

26 AUG 2020 12:02

PC Close Date & Time

26 AUG 2020 14:32

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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 98.2 °F

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

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

PC Time Stamp	26 AUG 2020 22:43
PC Open Date & Time	26 AUG 2020 15:27
PC Close Date & Time	27 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 06:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 22:32

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 18:36

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 05:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 00:06

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 01:21

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

26 AUG 2020 12:24

PC Open Date & Time

26 AUG 2020 12:02

PC Close Date & Time

26 AUG 2020 14:32

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

26 AUG 2020 22:43

PC Open Date & Time

26 AUG 2020 15:27

PC Close Date & Time

27 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

28 AUG 2020 06:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

28 AUG 2020 22:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

29 AUG 2020 18:37

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

31 AUG 2020 05:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

01 SEP 2020 00:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

02 SEP 2020 01:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 12:24
PC Open Date & Time	26 AUG 2020 12:02
PC Close Date & Time	26 AUG 2020 14:32

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 22:44
PC Open Date & Time	26 AUG 2020 15:27
PC Close Date & Time	27 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 06:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

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)

110 of 2423

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 22:34
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

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 ☒

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:38
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

114 of 2423

EAB) (1725)

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 05:56
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

116 of 2423

EAB) (1725)

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 00:07
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 01:22
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 15:18:31

Generated On: 09 Jun 2021 14:55:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:43 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:43
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3052044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	15:25 (24 HR)
Collection date and time (derived)	29 SEP 2020 15:25

US3052044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 SEP 2020 00:02:09

Patient Cloud Open Date & Time

30 SEP 2020 00:01

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

17 OCT 2020 17:59:58

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

31 OCT 2020 10:00:28

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 00:02:08
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:01:49

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 18:08:43

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 <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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

30 NOV 2020 12:05:51

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	06 DEC 2020 09:55:37
Patient Cloud Open Date & Time	06 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
142 of 2423	

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

16 DEC 2020 05:52:45

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

20 DEC 2020 00:01:46

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 15:06:41

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

03 JAN 2021 16:07:18

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

10 JAN 2021 00:02:27

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	19 JAN 2021 09:58:48
Patient Cloud Open Date & Time	17 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
149 of 2423	

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

25 JAN 2021 00:31:50

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

31 JAN 2021 03:27:48

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 12:19:22

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 20:06:29
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 16:05:12

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

28 FEB 2021 08:53:37

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

08 MAR 2021 16:37:06

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 12:52:00

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

21 MAR 2021 11:34:13

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 12:07:04

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

07 APR 2021 15:08:58

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

11 APR 2021 21:33:01

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 12:00:26

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Date and time of submission

25 APR 2021 07:36:59

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Date and time of submission

02 MAY 2021 06:31:01

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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="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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 <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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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°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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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°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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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="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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 <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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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="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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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°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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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 ☐

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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"/>

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3052044

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:55:29

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 08:53:18

US3052044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 DEC 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments LEFTVM

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 15:18:31

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

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

Visit date (dd MMM yyyy)	18 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 13:25:28

Generated On: 09 Jun 2021 14:55:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 MAR 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 08:46
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052044

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3052044

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	09:05 (24 HR)
Collection date and time (derived)	18 MAR 2021 09:05

US3052044

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:25:28

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:25:28

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:25:28

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 12:26:38

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 12:26:38

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Date of Contact	10 AUG 2020
Time of Contact	18:57
Date and Time of Contact (derived)	10 AUG 2020 18:57
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3052044

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3052044

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3052044

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Height	173 cm
Weight	91 kg
BMI (xxx.x)	30.40529

US3052044

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Height	173 cm
Weight	91 kg
BMI (xxx.x)	30.40529
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)	15 JAN 2021
Time of assessment (00:00-23:59)	11:49 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 11:49
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Height	173 cm
Weight	91 kg
BMI (xxx.x)	30.40529
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)	15 JAN 2021
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 12:59
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3052044

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 12:26 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 12:26

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

US3052044

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

15 JAN 2021 12:20

US3052044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	12:23
Collection Date and Time (derived)	15 JAN 2021 12:23

US3052044

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 15:18:31

Generated On: 09 Jun 2021 14:55:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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)	15 FEB 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 09:25
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:59:06

Generated On: 09 Jun 2021 14:55:29

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)	15 FEB 2021
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 10:38
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3052044

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3052044

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 09:47 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 09:47

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

US3052044

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 15:18:31

Generated On: 09 Jun 2021 14:55:29

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

MISSED

If Contact Not Made, please provide Comments

US3052044

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 15:18:31

Generated On: 09 Jun 2021 14:55:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052044

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:20:06

Generated On: 09 Jun 2021 14:55:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 20:20:07

Generated On: 09 Jun 2021 14:55:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:46 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 08:46
Temperature (<i>xxx.x</i>)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052044

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:20:06

Generated On: 09 Jun 2021 14:55:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3052044

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:20:06

Generated On: 09 Jun 2021 14:55:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	09:05 (24 HR)
Collection date and time (derived)	18 MAR 2021 09:05

US3052044

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 02:29:51

Generated On: 09 Jun 2021 14:55:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:35:18

Generated On: 09 Jun 2021 14:55:29

AEID	USA-US117-2021-MRNA-1273-P30 1000008
Adverse event	COPD EXACERBATION
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)	06 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	10 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:35:18

Generated On: 09 Jun 2021 14:55:29

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
SUBJECT REPORTED BEING ADMITTED TO THE HOSPITAL FOR A COPD EXACERBATION ON 06DEC2020.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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

Yes ☒

No ☐

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

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication PLAVIX

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration SEE NOTE

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

If dose unit is Other, specify SLIDING SCALE

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) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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 (5)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HISTORY OF CABG

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication CARVEDILOL

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

Dose per administration 6.25

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 (6)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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 (7)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication CHRONIC SINUSITIS

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) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication ISOSORBIDE DINITRATE

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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 (10)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

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 (10)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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 (11)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COPD

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 (11)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication RANOLAZINE

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication AMLODIPINE

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication EZETIMIBE

Prophylaxis Yes ☒
No ☐

Indication HISTORY OF CABG

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication FLONASE

Prophylaxis Yes ☒
No ☐

Indication SINUSITIS

Dose per administration 2

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

If dose unit is Other, specify SPRAY

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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) _____		
Start date completely unknown		True
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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication MAINTENENCE

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	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) _____		
Start date completely unknown		True
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 (18)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication SPIRIVA

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2.5

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

If dose unit is Other, specify MCG

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

Name of Medication IPRATROPIUM
BROMIDE/ALBUTEROL MIX

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 16:22:57

Generated On: 09 Jun 2021 14:55:29

	Intraocular	<input type="checkbox"/>
	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)	29 MAR 2021	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3052044

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3052044

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

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

US3052044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Feb 2021 07:59:05

Generated On: 09 Jun 2021 14:55:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

SAEID	USA-US117-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

SAEID	USA-US117-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 13:45
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

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 13:46:58

Generated On: 09 Jun 2021 14:55:29

SAEID	USA-US117-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	21/APR/2021 09:58
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

US3052044 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052044

Form: Participant Creation

Generated On: 09 Jun 2021 14:55:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'US3052044'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 15:14:22

US3052044

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Jul 2020 16:17:09

US3052044

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:23

US3052044

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	amy sheets (b) (4)	31 Jul 2020 16:17:09

US3052044

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'SCRN'	System	31 Jul 2020 16:17:09

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:24

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	12 Oct 2020 07:36:02
Query 'Per CDM: Please complete this form.' answered with 'completed' (Site from DM).	Avia McClain-Stocker	09 Oct 2020 15:57:48
User entered '64'	(b) (4)	18 Aug 2020 18:44:20
User opened query 'Per CDM: Please complete this form.' (Site from DM).	amy sheets (b) (4)	18 Aug 2020 11:37:04

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'YEARS'	System	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered '64'	System	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Male (M)'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'I'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:44:20

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'Jul 2020'	System	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered '2020'	System	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Amendment 1 (1)'	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	31 Jul 2020 16:17:28

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:23

US3052044

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'I'	System	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:55:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:45:35

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Non-occupational environmental exposures, PT: Exposure to chemical pollution, LLT: Asbestos exposure - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:44:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:44:28
Data point term sent to Coder	System	23 Oct 2020 20:43:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Exposures, chemical injuries and poisoning, HLT: Non-occupational environmental exposures, PT: Exposure to chemical pollution, LLT: Asbestos exposure - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:42:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:42:43
Query 'Requery: For coding purposes, please split ASBESTOS EXPOSURE WITH COPD - CONTROLLED WITH INHALERS into separate entries. 1. ASBESTOS EXPOSURE and 2. COPD' canceled (Site from System).	Coder Import (b) (4)	23 Oct 2020 20:42:30
Data point term sent to Coder	System	23 Oct 2020 20:42:14
User entered 'ASBESTOS EXPOSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 20:42:03
User opened query 'Requery: For coding purposes, please split ASBESTOS EXPOSURE WITH COPD - CONTROLLED WITH INHALERS into separate entries. 1. ASBESTOS EXPOSURE and 2. COPD' (Site from System).	Coder Import (b) (4)	18 Oct 2020 23:53:23
Data point term sent to Coder	System	11 Oct 2020 00:08:23
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' (Site from System).	System	11 Oct 2020 00:08:03
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' answered with 'there is only one event noted' (Site from System).	amy sheets (b) (4)	11 Oct 2020 00:08:03

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). Data point term sent to Coder	Coder Import (b) (4)	19 Aug 2020 21:24:04
User entered 'Asbestos exposure with COPD - controlled with inhalers'	System amy sheets (b) (4)	18 Aug 2020 18:47:03 18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 1995'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
Signature has been broken.	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 16:41:44
	Judith Borger (b) (4)	23 Feb 2021 07:59:06
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 18:46:40
	(b) (4)	

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
Signature has been broken.	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 16:41:51
	Judith Borger (b) (4)	23 Feb 2021 07:59:06
	(b) (4)	
User entered '0'	amy sheets (b) (4)	18 Aug 2020 18:46:40
	(b) (4)	

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:46:40

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:58:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: CABG - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:52:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:52:32
Data point term sent to Coder	System	23 Oct 2020 20:51:24
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'cardiac blood vessel stricture is the condition. it has been added.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:50:28
User entered 'CABG surgery' reason for change:	(b) (4), (b) (6)	23 Oct 2020 20:50:24
Data Entry Error		
Data point term sent to Coder	System	23 Oct 2020 20:50:22
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 20:49:58
User entered 'CABG' reason for change: Data Entry Error		23 Oct 2020 20:49:58
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		27 Aug 2020 13:07:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: CABG - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:32:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:32:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Aug 2020 18:48:04
User entered 'CABG x 2'	amy sheets (b) (4)	18 Aug 2020 18:47:31
	(b) (4)	

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '05 Apr 2009'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 20:50:24
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Aug 2020 18:47:31
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
	(b) (4)	
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 20:53:24
User entered '05 Apr 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 20:53:24
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 20:52:44
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 20:52:44
User entered 'UN UNK 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 20:52:44
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 20:50:24
User entered 'un Apr 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 20:50:24
User entered empty.	amy sheets (b) (4)	18 Aug 2020 18:47:31
	(b) (4)	

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Apr 2009'	System	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2009'	System	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Apr 2009'	System	23 Oct 2020 20:53:24
User entered 'Jan 2009'	System	23 Oct 2020 20:52:44
User entered 'Apr 2009'	System	23 Oct 2020 20:50:24
User entered empty.	System	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2009'	System	23 Oct 2020 20:50:24
User entered empty.	System	18 Aug 2020 18:47:31

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 17:23:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 17:23:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 13:41:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 13:41:31
User closed query 'Per MM: please clarify MH term and update as needed ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:00:09
User closed query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. " ' (Site from DM).		27 Oct 2020 17:59:25
User closed query ""Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).		27 Oct 2020 17:59:18
Data point term sent to Coder	System	23 Oct 2020 20:58:40
Query 'Per MM: please clarify MH term and update as needed ' answered with 'resolved' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:58:01
User entered 'STENT PLACEMENT - HEART' reason for change: Data Entry Error		23 Oct 2020 20:57:56

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
Query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. " ' answered with 'associated condition is cardiac blood vessel stricture' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:56:37
Data point term sent to Coder	System	23 Oct 2020 20:56:35
Query "'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' answered with 'Resolved. Stent was in the heart.' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 20:56:17
User entered 'STENT - HEART' reason for change: Data Entry Error		23 Oct 2020 20:56:09
User opened query 'Per MM: please clarify MH term and update as needed ' (Site from DM).		23 Oct 2020 20:56:09
User opened query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. " ' (Site from DM).		17 Sep 2020 12:43:47
User opened query "'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).		27 Aug 2020 13:13:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 13:12:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	23 Aug 2020 07:23:43
Data point term sent to Coder	System	23 Aug 2020 07:23:43
User entered 'Stent'	amy sheets (b) (4)	18 Aug 2020 18:52:20
	(b) (4)	18 Aug 2020 18:51:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 2014'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2014'	System	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 12:55:31
User entered empty.	System	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:51:48

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:08:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:08:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:41:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:41:31
User closed query 'Per MM: please clarify MH term and update as needed ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:45:08
User closed query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. " ' (Site from DM).		29 Oct 2020 05:25:58
User closed query ""Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).		29 Oct 2020 05:16:41
Query ""Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' answered with 'stent was placed in heart' (Site from DM).		23 Oct 2020 20:58:51
Query 'Per MM: please clarify MH term and update as needed ' answered with 'resolved' (Site from DM).		23 Oct 2020 20:58:42
Data point term sent to Coder	System	23 Oct 2020 20:58:40

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
Query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. " ' answered with 'associated condition is cardiac blood vessel stricture' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 20:58:39
User entered 'STENT PLACEMENT - HEART' reason for change: Per Query Resolution		23 Oct 2020 20:58:20
User opened query 'Per MM: please clarify MH term and update as needed' (Site from DM).		17 Sep 2020 12:43:27
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. "' (Site from DM).		27 Aug 2020 13:14:52
User opened query "'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of STENT. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).		27 Aug 2020 13:14:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:23:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:23:43
Data point term sent to Coder	System	18 Aug 2020 18:53:29
User entered 'Stent'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 2015'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	18 Aug 2020 18:53:21

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2015'	System	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 12:56:16
User entered empty.	System	18 Aug 2020 18:53:21

US3052044

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:53:21

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 10:55:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 10:55:12
User closed query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:29:54
Query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable. ' answered with 'resolved' (Site from DM).		23 Oct 2020 20:59:43
Data point term sent to Coder	System	23 Oct 2020 20:59:43
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 20:59:39
User entered 'MELANOMA - middle toe on right foot' reason for change: Data Entry Error		23 Oct 2020 20:59:39
User opened query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable. ' (Site from DM).		27 Aug 2020 13:18:48
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	18 Aug 2020 23:25:25
Data point term sent to Coder	System	18 Aug 2020 18:54:30
User entered 'Melanoma'	amy sheets (b) (4)	18 Aug 2020 18:53:54
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 1995'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 20:59:39
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Aug 2020 18:53:54
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 1995' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:59:39
User entered empty.	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:53:54

US3052044

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	18 Aug 2020 18:53:54

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	23 Oct 2020 20:59:39
User entered empty.	System	18 Aug 2020 18:53:54

US3052044

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	23 Oct 2020 20:59:39
User entered empty.	System	18 Aug 2020 18:53:54

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	20 Nov 2020 00:53:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 00:53:01
User closed query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable.	(b) (4), (b) (6)	29 Oct 2020 05:30:13
' (Site from DM).		
Data point term sent to Coder	System	23 Oct 2020 21:06:49
Query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable.	(b) (4), (b) (6)	23 Oct 2020 21:05:57
' answered with 'resolved' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 21:05:49
User entered 'MELANOMA - LEFT CHEST' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:05:49
User opened query 'Per DM CLR: Please review and update Medical History Specify Details to reflect the location of MELANOMA. Please reconcile with the AE or ConMed eCRF if applicable.	(b) (4), (b) (6)	27 Aug 2020 13:19:53
' (Site from DM).		
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:26
Data point term sent to Coder	System	18 Aug 2020 18:54:34

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EAB) (1725)

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User entered 'Melanoma'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 2005'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 21:05:49
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Aug 2020 18:54:08
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2005' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:05:49
User entered empty.	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	23 Oct 2020 21:05:49
User entered empty.	System	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	23 Oct 2020 21:05:49
User entered empty.	System	18 Aug 2020 18:54:08

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Dupuytren's contracture, LLT: Dupuytren's contracture - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 21:23:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 21:23:39
Data point term sent to Coder	System	23 Oct 2020 21:07:50
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 21:07:03
User entered 'B/L DUPUYTREN'S DISEASE - BOTH HANDS' reason for change: New Information		23 Oct 2020 21:07:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Dupuytren's contracture, LLT: Dupuytren's contracture - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 06:40:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 06:40:16
Data point term sent to Coder	System	18 Aug 2020 18:59:47
User entered 'Dupuytren's Disease - Right Hand'	amy sheets (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2013' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:07:03
User entered 'un UNK 2018'	amy sheets (b) (4) (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	23 Oct 2020 21:07:03
User entered 'Jan 2018'	System	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2013'	System	23 Oct 2020 21:07:03
User entered '2018'	System	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 18:59:33

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Diabetes mellitus insulin-dependent - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Aug 2020 03:54:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 03:54:42
Data point term sent to Coder	System	18 Aug 2020 19:00:49
User entered 'Diabetes with Insulin pump'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 2002'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2002'	System	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 19:00:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Fascial and bursal therapeutic procedures, PT: Dupuytren's contracture operation, LLT: Dupuytren's contracture operation - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:30:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:30:59
User closed query 'Per MM: please split and record each condition separately' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:03:08
Data point term sent to Coder	System	23 Oct 2020 21:09:53
Query 'Per MM: please split and record each condition separately' answered with 'resolved' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:09:08
User closed query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.' (Site from System).	System	23 Oct 2020 21:09:04
Query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.' answered with 'resolved' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 21:09:04
User entered 'DUPUTRYEN'S DISEASE SURGERY - BOTH HANDS' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 21:08:56
Data point term sent to Coder	System	09 Oct 2020 16:09:13
User entered 'DUPUTRYEN'S, BILATERAL ROTATOR CUFFS,' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:08:47
User opened query 'Per MM: please split and record each condition separately' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:42:51
User opened query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.' (Site from System).	Coder Import (b) (4)	19 Aug 2020 21:45:05
Data point term sent to Coder	System	18 Aug 2020 19:01:54
User entered 'CABG, Stents, Duputryen's, Bilateral rotator cuffs, inguinal hernia'	amy sheets (b) (4)	18 Aug 2020 19:01:46

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EAB) (1725)

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:08:56
User entered empty.	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	23 Oct 2020 21:09:22
User entered '0' reason for change: Data Entry Error	System	23 Oct 2020 21:09:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:09:22
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	23 Oct 2020 21:08:56
User entered '1'	amy sheets (b) (4)	18 Aug 2020 19:01:46
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	09 Oct 2020 16:08:47
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Aug 2020 19:01:46
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2018' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:08:56
User entered empty.	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	23 Oct 2020 21:09:31
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	23 Oct 2020 21:09:31
User opened query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	System	23 Oct 2020 21:08:56
User entered '1' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:08:47
User entered '0'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	23 Oct 2020 21:08:56
User entered empty.	System	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2018'	System	23 Oct 2020 21:08:56
User entered empty.	System	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	23 Oct 2020 21:08:56
User entered empty.	System	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2018'	System	23 Oct 2020 21:08:56
User entered empty.	System	18 Aug 2020 19:01:46

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Mar 2021 18:15:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 18:15:56
Data point term sent to Coder	System	05 Mar 2021 18:14:59
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 18:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:14:48
User entered 'coronary artery disease' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 18:14:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
Data point term sent to Coder	System	23 Oct 2020 21:20:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:40
Data point term sent to Coder	System	23 Oct 2020 21:19:13
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 21:19:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:19:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: CABG - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:11:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Oct 2020 16:11:23
Data point term sent to Coder	System	09 Oct 2020 16:10:17
User entered 'CABG'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	05 Mar 2021 18:14:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	23 Oct 2020 21:19:06
User entered empty.	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '1' reason for change: Data Entry Error	(b) (4)	05 Mar 2021 18:14:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User entered '0' reason for change: Data Entry Error		23 Oct 2020 21:19:06
User entered '1'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	05 Mar 2021 18:14:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 18:14:48
DataPoint activated with code reason code Data required.		05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	23 Oct 2020 21:19:06
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:40
User entered empty.	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:40
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:19:06
User entered '1'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:10:10

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User entered empty.	System	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User entered empty.	System	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:40
User entered empty.	System	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:14:27
DataPoint inactivated with code reason code Data no required.		23 Oct 2020 21:19:40
User entered empty.	System	09 Oct 2020 16:10:10

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Oct 2020 21:21:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:21:31
Data point term sent to Coder	System	23 Oct 2020 21:20:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:12:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:12:30
Data point term sent to Coder	System	09 Oct 2020 16:11:19
User entered 'inguinal hernia'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:25
User entered empty.	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:25
User entered 'I'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:25
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:25
User entered empty.	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Oct 2020 21:19:25
User entered 'I'	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:25
User entered empty.	System	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data no required.		23 Oct 2020 21:19:25
User entered empty.	System	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:25
User entered empty.	System	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Oct 2020 21:19:33
DataPoint inactivated with code reason code Data not required.		23 Oct 2020 21:19:25
User entered empty.	System	09 Oct 2020 16:11:13

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 05:43:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 05:43:50
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 20:44:18
User entered 'COPD due to Asbestos exposure'	(b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 20:43:51

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery stenosis, LLT: Coronary artery stenosis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Nov 2020 06:12:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:12:32
Data point term sent to Coder	System	23 Oct 2020 20:52:26
User entered 'CARDIAC BLOOD VESSEL STRICTURE'	(b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2009'	System	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2015'	System	23 Oct 2020 20:51:54

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Malignant melanoma excision - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Oct 2020 03:55:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:55:30
Data point term sent to Coder	System	23 Oct 2020 21:01:45
User entered 'melanoma removal surgery - middle toe right foot'	(b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
	(b) (4)	
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 21:01:24
User entered 'UN UNK 1995' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:01:24
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Oct 2020 21:01:15
User entered 'UN UNK 1985'	(b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	23 Oct 2020 21:01:24
User entered 'Jan 1985'	System	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '1995'	System	23 Oct 2020 21:01:24
User entered '1985'	System	23 Oct 2020 21:01:15

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Malignant melanoma excision - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Oct 2020 03:54:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:54:30
Data point term sent to Coder	System	23 Oct 2020 21:02:46
User entered 'MELANOMA REMOVAL SURGERY - LEFT CHEST'	(b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	23 Oct 2020 21:02:07

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Oct 2020 04:21:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:21:24
Data point term sent to Coder	System	23 Oct 2020 21:17:07
User entered 'ROTATOR CUFF SURGERY - LEFT SHOULDER'	(b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2002'	System	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2002'	System	23 Oct 2020 21:16:41

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

Condition

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Oct 2020 04:21:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:21:24
Data point term sent to Coder	System	23 Oct 2020 21:18:09
User entered 'ROTATOR CUFF INJURY - RIGHT SHOULDER'	(b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2005'	System	23 Oct 2020 21:17:15

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Oct 2020 21:22:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:22:33
Data point term sent to Coder	System	23 Oct 2020 21:21:18
User entered 'HYPERTENSION'	(b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered '2007'	System	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:20:57

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Oct 2020 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:51:41
Data point term sent to Coder	System	23 Oct 2020 21:50:55
User entered 'CHRONIC SINUSITIS'	(b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 21:50:27

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Mar 2021 17:52:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 17:52:47
Data point term sent to Coder	System	23 Mar 2021 17:52:29
User entered 'vertigo'	amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	23 Mar 2021 17:52:10
	(b) (4)	

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:52:10

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	12 Oct 2020 07:36:09
Query 'Per CDM: Please complete this form.' answered with 'completed' (Site from DM).	Avia McClain-Stocker	09 Oct 2020 15:58:20
User entered 'Yes (Y)'	(b) (4)	18 Aug 2020 19:02:41
User opened query 'Per CDM: Please complete this form.' (Site from DM).	amy sheets (b) (4)	18 Aug 2020 11:36:49

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	amy sheets (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10:59'	amy sheets (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered '31 Jul 2020 10:59'	System	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '69' in	(b) (4) amy sheets (b) (4)	18 Aug 2020 19:02:41
DataPoint set to visible.	(b) (4) System	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '214' lb	amy sheets (b) (4)	18 Aug 2020 19:02:41
DataPoint set to visible.	System	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
Amendment Manager: User entered '31.66835'	System	16 Sep 2020 23:39:40
User entered '31.7'	System	18 Aug 2020 19:02:41
DataPoint set to visible.	System	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'kg/m2'	System	18 Aug 2020 19:02:41
DataPoint set to visible.	System	31 Jul 2020 16:17:35

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
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 for TEMPERATURE, the unit should not remain. Please review and update as appropriate.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 07:36:11
' (Site from DM).		
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 for TEMPERATURE, the unit should not remain. Please review and update as appropriate.	Avia McClain-Stocker (b) (4)	09 Oct 2020 15:58:30
' answered with 'Screening and Day 1 same day. Updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 15:58:13
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 for TEMPERATURE, the unit should not remain. Please review and update as appropriate.	(b) (4), (b) (6)	08 Oct 2020 13:08:16
' (Site from DM).		
User entered '98.6' F	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 15:58:13
User entered 'Oral (Oral)'	amy sheets (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 15:58:13
User entered '73'	amy sheets (b) (4)	18 Aug 2020 19:02:41
	(b) (4)	

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'bpm'	System	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 15:58:13
User entered '12'	Avia McClain-Stocker (b) (4)	18 Aug 2020 19:02:41
	amy sheets (b) (4)	
	(b) (4)	

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'breaths/min'	System	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	09 Oct 2020 15:58:13
Query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' answered by data change (Site from System).	System	09 Oct 2020 15:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 15:58:13
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	18 Aug 2020 19:02:41
User entered '165'	amy sheets (b) (4)	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'mmHg'	System	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 15:58:13
User entered '88'	Avia McClain-Stocker (b) (4)	18 Aug 2020 19:02:41
	amy sheets (b) (4)	
	(b) (4)	

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User entered 'mmHg'	System	18 Aug 2020 19:02:41

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23

US3052044

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23

US3052044

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:03:00

US3052044

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 11:49:16
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 16:15:07
User entered '31 Jul 2020'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:00

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

[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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

[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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

[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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

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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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

[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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

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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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

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 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '0'	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:09:23
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:03:36

US3052044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:55

US3052044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:55

US3052044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:03:55

US3052044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'VISIT1'	System	18 Aug 2020 19:03:55

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:25

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:29:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:29:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 15:14:25
User entered '142456' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 15:14:25

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

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)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:04:48

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

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)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:04:48

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:04:48

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:04:48

US3052044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:04:48

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 16:00:19
User entered '69' in	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Avia McClain-Stocker (b) (4)	09 Oct 2020 16:00:19
User entered '214' lb	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 16:00:19
User entered '69' in	Avia McClain-Stocker (b) (4)	
	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 16:00:19
User entered '214' lb	Avia McClain-Stocker (b) (4)	
	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Pre-Dose (PREDOSE)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10:59'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '31 Jul 2020 10:59'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.6' F	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '73'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'bpm'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'breaths/min'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	16 Sep 2020 23:39:40
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:40
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Aug 2020 19:07:04
User entered '165'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '88'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 16:00:19
User entered '69' in	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 16:00:19
User entered '214' lb	Avia McClain-Stocker (b) (4)	
	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Post-Dose (POSTDOSE)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:35
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 19:07:04
User entered '12:32'	amy sheets (b) (4)	18 Aug 2020 19:07:04
	(b) (4)	

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '31 Jul 2020 12:32'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.8' F	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '59'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'bpm'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '16'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'breaths/min'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	16 Sep 2020 23:39:40
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:40
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Aug 2020 19:07:04
User entered '156'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '84'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	18 Aug 2020 19:07:04

US3052044

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:21

US3052044

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:07:21

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

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)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:59'	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) amy sheets (b) (4) (b) (4)	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'ONCE'	System	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 16:18:03

US3052044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:08:44

US3052044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:02:07
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'Collection was shipped.' (Site from DM).	Avia McClain-Stocker (b) (4)	07 Oct 2020 19:39:26
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:00:12
User entered '31 Jul 2020'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:08:44

US3052044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:51'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:08:44

US3052044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '31 Jul 2020 11:51'	System	18 Aug 2020 19:08:44

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '31 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:27'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '31 Jul 2020 11:27'	System	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered empty.	System	18 Aug 2020 19:09:03

US3052044

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:09:12

US3052044

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	18 Aug 2020 19:09:12

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:33:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a06b5767-07e8-453c-953d-109c88a53e56' User entered 'Yes (Y)'	System	31 Jul 2020 16:34:10
	System	31 Jul 2020 16:34:10

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:33:56', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a06b5767-07e8-453c-953d-109c88a53e56' User entered '98.8'	System	31 Jul 2020 16:34:10
	System	31 Jul 2020 16:34:10

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:03', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a06b5767-07e8-453c-953d-109c88a53e56'	System	31 Jul 2020 16:34:10
User entered 'No (N)'	System	31 Jul 2020 16:34:10

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a06b5767-07e8-453c-953d-109c88a53e56' User entered '31 Jul 2020 12:34'	System	31 Jul 2020 16:34:10
	System	31 Jul 2020 16:34:10

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 12:19'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 14:49'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:41:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '166b8cc5-c4c3-434b-a396-be1288b82886' User entered 'Yes (Y)'	System	31 Jul 2020 23:41:42
	System	31 Jul 2020 23:41:42

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:41:25', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '166b8cc5-c4c3-434b-a396-be1288b82886' User entered '98.0'	System	31 Jul 2020 23:41:42
	System	31 Jul 2020 23:41:42

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:41:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '166b8cc5-c4c3-434b-a396-be1288b82886' User entered 'No (N)'	System	31 Jul 2020 23:41:42
	System	31 Jul 2020 23:41:42

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:41:38', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '166b8cc5-c4c3-434b-a396-be1288b82886' User entered '31 Jul 2020 19:41'	System	31 Jul 2020 23:41:42
	System	31 Jul 2020 23:41:42

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 15:44'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 2'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:31:54', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e23e489-80b9-453e-bfb2-3a10d4557d3a' User entered 'Yes (Y)'	System	02 Aug 2020 01:32:15
	System	02 Aug 2020 01:32:15

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:03', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e23e489-80b9-453e-bfb2-3a10d4557d3a' User entered '97.8'	System	02 Aug 2020 01:32:15
	System	02 Aug 2020 01:32:15

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e23e489-80b9-453e-bfb2-3a10d4557d3a' User entered 'No (N)'	System	02 Aug 2020 01:32:15
	System	02 Aug 2020 01:32:15

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e23e489-80b9-453e-bfb2-3a10d4557d3a' User entered '01 Aug 2020 21:32'	System	02 Aug 2020 01:32:15
	System	02 Aug 2020 01:32:15

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 3'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:34:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '33c89539-8596-408e-ab14-aa5b6e2b4cb0'	System	03 Aug 2020 01:34:56
User entered 'Yes (Y)'	System	03 Aug 2020 01:34:56

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:34:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '33c89539-8596-408e-ab14-aa5b6e2b4cb0' User entered '98.0'	System	03 Aug 2020 01:34:56
	System	03 Aug 2020 01:34:56

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:34:49', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '33c89539-8596-408e-ab14-aa5b6e2b4cb0'	System	03 Aug 2020 01:34:56
User entered 'No (N)'	System	03 Aug 2020 01:34:56

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:34:54', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '33c89539-8596-408e-ab14-aa5b6e2b4cb0' User entered '02 Aug 2020 21:34'	System	03 Aug 2020 01:34:56
	System	03 Aug 2020 01:34:56

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 4'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bc7e35d5-71dd-463c-af79-43e3004a675c' User entered 'Yes (Y)'	System	04 Aug 2020 00:13:37
	System	04 Aug 2020 00:13:37

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bc7e35d5-71dd-463c-af79-43e3004a675c' User entered '98.4'	System	04 Aug 2020 00:13:37
	System	04 Aug 2020 00:13:37

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:28', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bc7e35d5-71dd-463c-af79-43e3004a675c' User entered 'No (N)'	System	04 Aug 2020 00:13:37
	System	04 Aug 2020 00:13:37

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:33', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bc7e35d5-71dd-463c-af79-43e3004a675c' User entered '03 Aug 2020 20:13'	System	04 Aug 2020 00:13:37
	System	04 Aug 2020 00:13:37

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 5'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c6b06e0c-4c2a-4a24-bf2d-8aefbb2336c5' User entered 'Yes (Y)'	System	05 Aug 2020 00:07:22
	System	05 Aug 2020 00:07:22

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c6b06e0c-4c2a-4a24-bf2d-8aefbb2336c5' User entered '97.8'	System	05 Aug 2020 00:07:22
	System	05 Aug 2020 00:07:22

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:14', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c6b06e0c-4c2a-4a24-bf2d-8aefbb2336c5'	System	05 Aug 2020 00:07:22
User entered 'No (N)'	System	05 Aug 2020 00:07:22

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c6b06e0c-4c2a-4a24-bf2d-8aefbb2336c5'	System	05 Aug 2020 00:07:22
User entered '04 Aug 2020 20:07'	System	05 Aug 2020 00:07:22

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 6'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:35:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7999ab8d-35c9-4a5b-ad5b-6f44295ce833'	System	06 Aug 2020 13:36:01
User entered 'Yes (Y)'	System	06 Aug 2020 13:36:01

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:35:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7999ab8d-35c9-4a5b-ad5b-6f44295ce833' User entered '97.9'	System	06 Aug 2020 13:36:01
	System	06 Aug 2020 13:36:01

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:35:56', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7999ab8d-35c9-4a5b-ad5b-6f44295ce833'	System	06 Aug 2020 13:36:01
User entered 'No (N)'	System	06 Aug 2020 13:36:01

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:35:59', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7999ab8d-35c9-4a5b-ad5b-6f44295ce833'	System	06 Aug 2020 13:36:01
User entered '06 Aug 2020 09:35'	System	06 Aug 2020 13:36:01

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 7'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T23:59:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ca76a23f-858c-4679-b3a3-6c1f1f2753e2'	System	07 Aug 2020 04:00:07
User entered 'Yes (Y)'	System	07 Aug 2020 04:00:07

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T23:59:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ca76a23f-858c-4679-b3a3-6c1f1f2753e2' User entered '98.4'	System	07 Aug 2020 04:00:07
	System	07 Aug 2020 04:00:07

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T23:59:56', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ca76a23f-858c-4679-b3a3-6c1f1f2753e2'	System	07 Aug 2020 04:00:07
User entered 'No (N)'	System	07 Aug 2020 04:00:07

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ca76a23f-858c-4679-b3a3-6c1f1f2753e2'	System	07 Aug 2020 04:00:07
User entered '07 Aug 2020 00:00'	System	07 Aug 2020 04:00:07

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:31:19', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '62582fb0-2010-4181-a502-1349cf275491'	System	31 Jul 2020 16:33:32
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 16:33:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:32:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '62582fb0-2010-4181-a502-1349cf275491' User entered 'No (N)'	System	31 Jul 2020 16:33:32
	System	31 Jul 2020 16:33:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:33:01', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '62582fb0-2010-4181-a502-1349cf275491' User entered 'No (N)'	System	31 Jul 2020 16:33:32
	System	31 Jul 2020 16:33:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:33:06', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '62582fb0-2010-4181-a502-1349cf275491'	System	31 Jul 2020 16:33:32
User entered 'None (1)'	System	31 Jul 2020 16:33:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:33:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '62582fb0-2010-4181-a502-1349cf275491' User entered '31 Jul 2020 12:33'	System	31 Jul 2020 16:33:32
	System	31 Jul 2020 16:33:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 12:19'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 14:49'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:42:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ef3dcf48-25b2-45e5-9da7-6b2547080ece'	System	31 Jul 2020 23:43:22
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 23:43:22

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:42:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ef3dcf48-25b2-45e5-9da7-6b2547080ece' User entered 'No (N)'	System	31 Jul 2020 23:43:22
	System	31 Jul 2020 23:43:22

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:42:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ef3dcf48-25b2-45e5-9da7-6b2547080ece' User entered 'No (N)'	System	31 Jul 2020 23:43:22
	System	31 Jul 2020 23:43:22

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ef3dcf48-25b2-45e5-9da7-6b2547080ece' User entered 'None (1)'	System	31 Jul 2020 23:43:22
	System	31 Jul 2020 23:43:22

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ef3dcf48-25b2-45e5-9da7-6b2547080ece' User entered '31 Jul 2020 19:43'	System	31 Jul 2020 23:43:22
	System	31 Jul 2020 23:43:22

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 15:44'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 2'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '14286116-6dd4-4243-8075-b3ad39667466'	System	02 Aug 2020 01:32:52
User entered 'None (1)'	System	02 Aug 2020 01:32:52

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '14286116-6dd4-4243-8075-b3ad39667466' User entered 'No (N)'	System	02 Aug 2020 01:32:52
	System	02 Aug 2020 01:32:52

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:30', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '14286116-6dd4-4243-8075-b3ad39667466' User entered 'No (N)'	System	02 Aug 2020 01:32:52
	System	02 Aug 2020 01:32:52

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '14286116-6dd4-4243-8075-b3ad39667466' User entered 'None (1)'	System	02 Aug 2020 01:32:52
	System	02 Aug 2020 01:32:52

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:32:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '14286116-6dd4-4243-8075-b3ad39667466' User entered '01 Aug 2020 21:32'	System	02 Aug 2020 01:32:52
	System	02 Aug 2020 01:32:52

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 3'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:02', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'aa60ed87-5bf7-4ce2-a9e9-fd07c01f6e7d' User entered 'None (1)'	System	03 Aug 2020 01:35:32
	System	03 Aug 2020 01:35:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'aa60ed87-5bf7-4ce2-a9e9-fd07c01f6e7d'	System	03 Aug 2020 01:35:32
User entered 'No (N)'	System	03 Aug 2020 01:35:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'aa60ed87-5bf7-4ce2-a9e9-fd07c01f6e7d' User entered 'No (N)'	System	03 Aug 2020 01:35:32
	System	03 Aug 2020 01:35:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'aa60ed87-5bf7-4ce2-a9e9-fd07c01f6e7d' User entered 'None (1)'	System	03 Aug 2020 01:35:32
	System	03 Aug 2020 01:35:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'aa60ed87-5bf7-4ce2-a9e9-fd07c01f6e7d' User entered '02 Aug 2020 21:35'	System	03 Aug 2020 01:35:32
	System	03 Aug 2020 01:35:32

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 4'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '970e3b64-eb2a-441f-98da-7c500ae5b4e4'	System	04 Aug 2020 00:14:14
User entered 'None (1)'	System	04 Aug 2020 00:14:14

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '970e3b64-eb2a-441f-98da-7c500ae5b4e4' User entered 'No (N)'	System	04 Aug 2020 00:14:14
	System	04 Aug 2020 00:14:14

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:13:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '970e3b64-eb2a-441f-98da-7c500ae5b4e4'	System	04 Aug 2020 00:14:14
User entered 'No (N)'	System	04 Aug 2020 00:14:14

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:07', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '970e3b64-eb2a-441f-98da-7c500ae5b4e4' User entered 'None (1)'	System	04 Aug 2020 00:14:14
	System	04 Aug 2020 00:14:14

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '970e3b64-eb2a-441f-98da-7c500ae5b4e4' User entered '03 Aug 2020 20:14'	System	04 Aug 2020 00:14:14
	System	04 Aug 2020 00:14:14

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 5'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:28', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '759e261d-1b2f-4772-8d22-097ef455e3a9'	System	05 Aug 2020 00:07:48
User entered 'None (1)'	System	05 Aug 2020 00:07:48

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '759e261d-1b2f-4772-8d22-097ef455e3a9'	System	05 Aug 2020 00:07:48
User entered 'No (N)'	System	05 Aug 2020 00:07:48

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '759e261d-1b2f-4772-8d22-097ef455e3a9'	System	05 Aug 2020 00:07:48
User entered 'No (N)'	System	05 Aug 2020 00:07:48

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '759e261d-1b2f-4772-8d22-097ef455e3a9'	System	05 Aug 2020 00:07:48
User entered 'None (1)'	System	05 Aug 2020 00:07:48

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '759e261d-1b2f-4772-8d22-097ef455e3a9' User entered '04 Aug 2020 20:07'	System	05 Aug 2020 00:07:48
	System	05 Aug 2020 00:07:48

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 6'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:05', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2b0938c2-1f1e-4589-bcbd-bfa20270e814' User entered 'None (1)'	System	06 Aug 2020 13:36:23
	System	06 Aug 2020 13:36:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2b0938c2-1f1e-4589-bcbd-bfa20270e814' User entered 'No (N)'	System	06 Aug 2020 13:36:23
	System	06 Aug 2020 13:36:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2b0938c2-1f1e-4589-bcbd-bfa20270e814' User entered 'No (N)'	System	06 Aug 2020 13:36:23
	System	06 Aug 2020 13:36:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2b0938c2-1f1e-4589-bcbd-bfa20270e814' User entered 'None (1)'	System	06 Aug 2020 13:36:23
	System	06 Aug 2020 13:36:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2b0938c2-1f1e-4589-bcbd-bfa20270e814' User entered '06 Aug 2020 09:36'	System	06 Aug 2020 13:36:23
	System	06 Aug 2020 13:36:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 7'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:07', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5f10612e-2304-44fb-bcae-0a5ae6a0ccfa'	System	07 Aug 2020 04:00:23
User entered 'None (1)'	System	07 Aug 2020 04:00:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5f10612e-2304-44fb-bcae-0a5ae6a0ccfa'	System	07 Aug 2020 04:00:23
User entered 'No (N)'	System	07 Aug 2020 04:00:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5f10612e-2304-44fb-bcae-0a5ae6a0ccfa'	System	07 Aug 2020 04:00:23
User entered 'No (N)'	System	07 Aug 2020 04:00:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5f10612e-2304-44fb-bcae-0a5ae6a0ccfa'	System	07 Aug 2020 04:00:23
User entered 'None (1)'	System	07 Aug 2020 04:00:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5f10612e-2304-44fb-bcae-0a5ae6a0ccfa' User entered '07 Aug 2020 00:00'	System	07 Aug 2020 04:00:23
	System	07 Aug 2020 04:00:23

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:17', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:25', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:29', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered 'None (0)'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629'	System	31 Jul 2020 16:34:52
User entered 'No (N)'	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T12:34:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bfbbd047-d8b4-4ccb-9f35-cd6b88ffb629' User entered '31 Jul 2020 12:34'	System	31 Jul 2020 16:34:52
	System	31 Jul 2020 16:34:52

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 12:19'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 14:49'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:30', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa'	System	31 Jul 2020 23:44:25
User entered 'No interference with activity (1)'	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered 'None (0)'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa'	System	31 Jul 2020 23:44:25
User entered 'No interference with activity (1)'	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered 'None (0)'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered 'None (0)'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:43:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered 'None (0)'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:44:04', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered 'No (N)'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-07-31T19:44:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '06ce3a27-c5c1-4a63-895d-387e0f48c7aa' User entered '31 Jul 2020 19:44'	System	31 Jul 2020 23:44:25
	System	31 Jul 2020 23:44:25

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Jul 2020 15:44'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 2'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:04', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:17', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:26', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'None (0)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:33', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered 'No (N)'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-01T21:33:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '408bcd2-7eea-4f96-9b97-299750ca1504'	System	02 Aug 2020 01:33:38
User entered '01 Aug 2020 21:33'	System	02 Aug 2020 01:33:38

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 3'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'None (0)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'No interference with activity (1)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'None (0)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'None (0)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:55', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'None (0)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:35:59', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'None (0)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:36:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered 'No (N)'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-02T21:36:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9b868ffd-9dc4-40ff-b2ac-0dead91893eb' User entered '02 Aug 2020 21:36'	System	03 Aug 2020 01:37:00
	System	03 Aug 2020 01:37:00

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 4'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:17', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'None (0)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b'	System	04 Aug 2020 00:14:54
User entered 'No interference with activity (1)'	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'None (0)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'None (0)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'None (0)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'None (0)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:49', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered 'No (N)'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-03T20:14:53', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'eccd5f84-e795-487c-9e85-8dc7e8bc8a9b' User entered '03 Aug 2020 20:14'	System	04 Aug 2020 00:14:54
	System	04 Aug 2020 00:14:54

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 5'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:07:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered 'None (0)'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:01', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3'	System	05 Aug 2020 00:08:29
User entered 'Some interference with activity (2)'	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:05', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered 'None (0)'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered 'None (0)'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered 'None (0)'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:17', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered 'None (0)'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3'	System	05 Aug 2020 00:08:29
User entered 'No (N)'	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-04T20:08:25', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7fbf045f-ba26-4a92-b488-0139a0dc3dc3' User entered '04 Aug 2020 20:08'	System	05 Aug 2020 00:08:29
	System	05 Aug 2020 00:08:29

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 6'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:28', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'None (0)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e'	System	06 Aug 2020 13:37:06
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'None (0)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'None (0)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'None (0)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'None (0)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:36:59', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered 'No (N)'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-06T09:37:02', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '045175c0-c9b1-4546-8bcf-753a20c40c1e' User entered '06 Aug 2020 09:37'	System	06 Aug 2020 13:37:06
	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 7'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'None (0)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:54', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered 'No (N)'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-07T00:00:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'be734b6a-c222-45c1-af46-e6620c530de9' User entered '07 Aug 2020 00:00'	System	07 Aug 2020 04:01:01
	System	07 Aug 2020 04:01:01

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	06 Aug 2020 13:37:06
User entered 'Day 8'	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-08T10:00:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '510ecd70-d5ab-4963-b621-a59b95a050c8' User entered 'No (N)'	System	08 Aug 2020 14:00:47
	System	08 Aug 2020 14:00:47

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-08T10:00:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '510ecd70-d5ab-4963-b621-a59b95a050c8' User entered '08 Aug 2020 10:00'	System	08 Aug 2020 14:00:47
	System	08 Aug 2020 14:00:47

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 13:37:06

US3052044

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 13:37:06

US3052044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:10:00

US3052044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10 Aug 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:10:00

US3052044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:10:00

US3052044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:10:00

US3052044

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:10:07

US3052044

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	18 Aug 2020 19:10:07

US3052044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:13
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	09 Oct 2020 13:45:47
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	07 Oct 2020 15:15:47
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 15:15:47
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	01 Oct 2020 17:56:08

US3052044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:13
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 15:15:47
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	07 Oct 2020 15:15:47
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 15:15:47
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 17:56:08
User entered '10 Aug 2020'	Avia McClain-Stocker (b) (4)	01 Oct 2020 17:56:08

US3052044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:13
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Avia McClain-Stocker	09 Oct 2020 13:45:47
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	Avia McClain-Stocker	07 Oct 2020 15:15:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Avia McClain-Stocker	01 Oct 2020 17:56:08
	(b) (4)	

US3052044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:13
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	09 Oct 2020 13:45:47
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	07 Oct 2020 15:15:54
Please review and reconcile.' (Site from System).		
User entered 'Safety call missed' reason for change: Data Entry Error	Avia McClain-Stocker	07 Oct 2020 15:15:54
User entered 'Safety call missed' reason for change: Data Entry Error	(b) (4)	
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	07 Oct 2020 15:15:47
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.		
Please review and reconcile.' (Site from System).		
User entered empty.	Avia McClain-Stocker	01 Oct 2020 17:56:08
User entered empty.	(b) (4)	

US3052044

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:13
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:14:45

US3052044

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:13
User entered 'I'	System	26 Aug 2020 16:14:45

US3052044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:57:59

US3052044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '24 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:57:59

US3052044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Avia McClain-Stocker	01 Oct 2020 17:57:59
	(b) (4)	

US3052044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:57:59

US3052044

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:14:54

US3052044

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	26 Aug 2020 16:14:54

US3052044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:07

US3052044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 11:59:36
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Aug 2020 16:15:07
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:07

US3052044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:07

US3052044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'VISIT2'	System	26 Aug 2020 16:15:07

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10:55'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '26 Aug 2020 10:55'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '97.7' F	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '72'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'bpm'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'breaths/min'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '124'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '75'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12:15'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '26 Aug 2020 12:15'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.4' F	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '74'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'bpm'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '22'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'breaths/min'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '122'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '63'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	01 Oct 2020 18:09:19

US3052044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:21

US3052044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:21

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

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)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:42'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '26 Aug 2020 11:42'	System	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'ONCE'	System	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:15:57

US3052044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:27

US3052044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:01:59
Query 'Per IMMUNO Lab Recon: it appears a samplemy sheets was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'labs were collected and reported by preclarus' (Site from DM).	(b) (4) (b) (4)	11 Oct 2020 00:09:16
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 16:06:57
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:27

US3052044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:28'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:27

US3052044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '26 Aug 2020 11:28'	System	26 Aug 2020 16:16:27

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:32'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '26 Aug 2020 11:32'	System	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered empty.	System	26 Aug 2020 16:16:47

US3052044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:16:55

US3052044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	26 Aug 2020 16:16:55

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:22:58', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5332f2b6-ae3c-4222-969b-86e25c0cdfc3' User entered 'Yes (Y)'	System	26 Aug 2020 16:23:29
	System	26 Aug 2020 16:23:29

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5332f2b6-ae3c-4222-969b-86e25c0cdfc3' User entered '98.4'	System	26 Aug 2020 16:23:29
	System	26 Aug 2020 16:23:29

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5332f2b6-ae3c-4222-969b-86e25c0cdfc3'	System	26 Aug 2020 16:23:29
User entered 'No (N)'	System	26 Aug 2020 16:23:29

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:25', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5332f2b6-ae3c-4222-969b-86e25c0cdfc3' User entered '26 Aug 2020 12:23'	System	26 Aug 2020 16:23:29
	System	26 Aug 2020 16:23:29

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 14:32'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:42:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '433c167e-b6d8-4413-a39f-2f1b17471b1d' User entered 'Yes (Y)'	System	27 Aug 2020 02:43:23
	System	27 Aug 2020 02:43:23

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:05', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '433c167e-b6d8-4413-a39f-2f1b17471b1d' User entered '98.2'	System	27 Aug 2020 02:43:23
	System	27 Aug 2020 02:43:23

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '433c167e-b6d8-4413-a39f-2f1b17471b1d' User entered 'No (N)'	System	27 Aug 2020 02:43:23
	System	27 Aug 2020 02:43:23

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '433c167e-b6d8-4413-a39f-2f1b17471b1d' User entered '26 Aug 2020 22:43'	System	27 Aug 2020 02:43:23
	System	27 Aug 2020 02:43:23

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 15:27'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 2'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T05:59:46', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c2d16376-5954-4a13-8a6c-fd5df38f253a' User entered 'Yes (Y)'	System	28 Aug 2020 10:00:19
	System	28 Aug 2020 10:00:19

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:03', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c2d16376-5954-4a13-8a6c-fd5df38f253a' User entered '98.2'	System	28 Aug 2020 10:00:19
	System	28 Aug 2020 10:00:19

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c2d16376-5954-4a13-8a6c-fd5df38f253a'	System	28 Aug 2020 10:00:19
User entered 'No (N)'	System	28 Aug 2020 10:00:19

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:14', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c2d16376-5954-4a13-8a6c-fd5df38f253a' User entered '28 Aug 2020 06:00'	System	28 Aug 2020 10:00:19
	System	28 Aug 2020 10:00:19

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 3'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:31:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '070890f7-016a-422e-bafa-f5c0c6dae2fd'	System	29 Aug 2020 02:32:53
User entered 'Yes (Y)'	System	29 Aug 2020 02:32:53

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:32:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '070890f7-016a-422e-bafa-f5c0c6dae2fd' User entered '98.3'	System	29 Aug 2020 02:32:53
	System	29 Aug 2020 02:32:53

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:32:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '070890f7-016a-422e-bafa-f5c0c6dae2fd'	System	29 Aug 2020 02:32:53
User entered 'No (N)'	System	29 Aug 2020 02:32:53

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:32:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '070890f7-016a-422e-bafa-f5c0c6dae2fd' User entered '28 Aug 2020 22:32'	System	29 Aug 2020 02:32:53
	System	29 Aug 2020 02:32:53

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 4'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:36:24', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3c56bf21-5c89-41b1-980c-160103e7d554'	System	29 Aug 2020 22:36:45
User entered 'Yes (Y)'	System	29 Aug 2020 22:36:45

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:36:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3c56bf21-5c89-41b1-980c-160103e7d554' User entered '97.9'	System	29 Aug 2020 22:36:45
	System	29 Aug 2020 22:36:45

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:36:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3c56bf21-5c89-41b1-980c-160103e7d554'	System	29 Aug 2020 22:36:45
User entered 'No (N)'	System	29 Aug 2020 22:36:45

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:36:42', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3c56bf21-5c89-41b1-980c-160103e7d554'	System	29 Aug 2020 22:36:45
User entered '29 Aug 2020 18:36'	System	29 Aug 2020 22:36:45

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 5'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:07', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '539cbfe0-8dd6-43c2-8194-ac8b7dbf5871' User entered 'Yes (Y)'	System	31 Aug 2020 09:55:24
	System	31 Aug 2020 09:55:24

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:14', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '539cbfe0-8dd6-43c2-8194-ac8b7dbf5871' User entered '98.3'	System	31 Aug 2020 09:55:24
	System	31 Aug 2020 09:55:24

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '539cbfe0-8dd6-43c2-8194-ac8b7dbf5871' User entered 'No (N)'	System	31 Aug 2020 09:55:24
	System	31 Aug 2020 09:55:24

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '539cbfe0-8dd6-43c2-8194-ac8b7dbf5871' User entered '31 Aug 2020 05:55'	System	31 Aug 2020 09:55:24
	System	31 Aug 2020 09:55:24

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 6'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1feae572-07d5-44ed-bd3c-9395a29c0050' User entered 'Yes (Y)'	System	01 Sep 2020 04:06:43
	System	01 Sep 2020 04:06:43

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1feae572-07d5-44ed-bd3c-9395a29c0050' User entered '98.5'	System	01 Sep 2020 04:06:43
	System	01 Sep 2020 04:06:43

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1feae572-07d5-44ed-bd3c-9395a29c0050'	System	01 Sep 2020 04:06:43
User entered 'No (N)'	System	01 Sep 2020 04:06:43

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:38', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1feae572-07d5-44ed-bd3c-9395a29c0050' User entered '01 Sep 2020 00:06'	System	01 Sep 2020 04:06:43
	System	01 Sep 2020 04:06:43

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 7'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:19', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '976a8c8e-14d1-4aed-a27b-4df8999e69cc' User entered 'Yes (Y)'	System	02 Sep 2020 05:21:39
	System	02 Sep 2020 05:21:39

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:30', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '976a8c8e-14d1-4aed-a27b-4df8999e69cc' User entered '98.6'	System	02 Sep 2020 05:21:39
	System	02 Sep 2020 05:21:39

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '976a8c8e-14d1-4aed-a27b-4df8999e69cc'	System	02 Sep 2020 05:21:39
User entered 'No (N)'	System	02 Sep 2020 05:21:39

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:38', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '976a8c8e-14d1-4aed-a27b-4df8999e69cc' User entered '02 Sep 2020 01:21'	System	02 Sep 2020 05:21:39
	System	02 Sep 2020 05:21:39

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '73d30c95-3120-4805-88f6-091c3b348e32'	System	26 Aug 2020 16:24:10
User entered 'None (1)'	System	26 Aug 2020 16:24:10

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '73d30c95-3120-4805-88f6-091c3b348e32'	System	26 Aug 2020 16:24:10
User entered 'No (N)'	System	26 Aug 2020 16:24:10

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '73d30c95-3120-4805-88f6-091c3b348e32'	System	26 Aug 2020 16:24:10
User entered 'No (N)'	System	26 Aug 2020 16:24:10

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:23:55', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '73d30c95-3120-4805-88f6-091c3b348e32'	System	26 Aug 2020 16:24:10
User entered 'None (1)'	System	26 Aug 2020 16:24:10

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:05', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '73d30c95-3120-4805-88f6-091c3b348e32'	System	26 Aug 2020 16:24:10
User entered '26 Aug 2020 12:24'	System	26 Aug 2020 16:24:10

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 14:32'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:26', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89c541f1-41b2-4d19-b236-afb0845ae616'	System	27 Aug 2020 02:43:49
User entered 'None (1)'	System	27 Aug 2020 02:43:49

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89c541f1-41b2-4d19-b236-afb0845ae616' User entered 'No (N)'	System	27 Aug 2020 02:43:49
	System	27 Aug 2020 02:43:49

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89c541f1-41b2-4d19-b236-afb0845ae616' User entered 'No (N)'	System	27 Aug 2020 02:43:49
	System	27 Aug 2020 02:43:49

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89c541f1-41b2-4d19-b236-afb0845ae616' User entered 'None (1)'	System	27 Aug 2020 02:43:49
	System	27 Aug 2020 02:43:49

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89c541f1-41b2-4d19-b236-afb0845ae616' User entered '26 Aug 2020 22:43'	System	27 Aug 2020 02:43:49
	System	27 Aug 2020 02:43:49

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 15:27'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 2'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f4dcc8b0-20b3-48ef-b1ba-99b3430c4fa4'	System	28 Aug 2020 10:00:40
User entered 'None (1)'	System	28 Aug 2020 10:00:40

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:24', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f4dcc8b0-20b3-48ef-b1ba-99b3430c4fa4'	System	28 Aug 2020 10:00:40
User entered 'No (N)'	System	28 Aug 2020 10:00:40

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:29', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f4dcc8b0-20b3-48ef-b1ba-99b3430c4fa4'	System	28 Aug 2020 10:00:40
User entered 'No (N)'	System	28 Aug 2020 10:00:40

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f4dcc8b0-20b3-48ef-b1ba-99b3430c4fa4'	System	28 Aug 2020 10:00:40
User entered 'None (1)'	System	28 Aug 2020 10:00:40

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f4dcc8b0-20b3-48ef-b1ba-99b3430c4fa4'	System	28 Aug 2020 10:00:40
User entered '28 Aug 2020 06:00'	System	28 Aug 2020 10:00:40

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 3'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:32:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bd6e8f75-ee20-46b8-a17c-a417960cc531' User entered 'None (1)'	System	29 Aug 2020 02:33:24
	System	29 Aug 2020 02:33:24

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bd6e8f75-ee20-46b8-a17c-a417960cc531' User entered 'No (N)'	System	29 Aug 2020 02:33:24
	System	29 Aug 2020 02:33:24

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bd6e8f75-ee20-46b8-a17c-a417960cc531' User entered 'No (N)'	System	29 Aug 2020 02:33:24
	System	29 Aug 2020 02:33:24

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:19', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bd6e8f75-ee20-46b8-a17c-a417960cc531' User entered 'None (1)'	System	29 Aug 2020 02:33:24
	System	29 Aug 2020 02:33:24

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'bd6e8f75-ee20-46b8-a17c-a417960cc531' User entered '28 Aug 2020 22:33'	System	29 Aug 2020 02:33:24
	System	29 Aug 2020 02:33:24

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 4'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:36:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5feea1ac-ddc1-4bbc-9dd5-c55db62bc5dd' User entered 'None (1)'	System	29 Aug 2020 22:37:55
	System	29 Aug 2020 22:37:55

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:37:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5feea1ac-ddc1-4bbc-9dd5-c55db62bc5dd' User entered 'No (N)'	System	29 Aug 2020 22:37:55
	System	29 Aug 2020 22:37:55

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:37:42', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5feea1ac-ddc1-4bbc-9dd5-c55db62bc5dd' User entered 'No (N)'	System	29 Aug 2020 22:37:55
	System	29 Aug 2020 22:37:55

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:37:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5feea1ac-ddc1-4bbc-9dd5-c55db62bc5dd' User entered 'None (1)'	System	29 Aug 2020 22:37:55
	System	29 Aug 2020 22:37:55

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:37:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '5feea1ac-ddc1-4bbc-9dd5-c55db62bc5dd' User entered '29 Aug 2020 18:37'	System	29 Aug 2020 22:37:55
	System	29 Aug 2020 22:37:55

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 5'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:26', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e1ee8c1f-5be7-48a0-a63c-b9a862657b5b' User entered 'None (1)'	System	31 Aug 2020 09:55:46
	System	31 Aug 2020 09:55:46

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e1ee8c1f-5be7-48a0-a63c-b9a862657b5b' User entered 'No (N)'	System	31 Aug 2020 09:55:46
	System	31 Aug 2020 09:55:46

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e1ee8c1f-5be7-48a0-a63c-b9a862657b5b' User entered 'No (N)'	System	31 Aug 2020 09:55:46
	System	31 Aug 2020 09:55:46

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e1ee8c1f-5be7-48a0-a63c-b9a862657b5b' User entered 'None (1)'	System	31 Aug 2020 09:55:46
	System	31 Aug 2020 09:55:46

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e1ee8c1f-5be7-48a0-a63c-b9a862657b5b' User entered '31 Aug 2020 05:55'	System	31 Aug 2020 09:55:46
	System	31 Aug 2020 09:55:46

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 6'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2eb8bf12-0bed-41be-857a-9722355bdc96' User entered 'None (1)'	System	01 Sep 2020 04:07:15
	System	01 Sep 2020 04:07:15

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:06:54', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2eb8bf12-0bed-41be-857a-9722355bdc96' User entered 'No (N)'	System	01 Sep 2020 04:07:15
	System	01 Sep 2020 04:07:15

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:01', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2eb8bf12-0bed-41be-857a-9722355bdc96' User entered 'No (N)'	System	01 Sep 2020 04:07:15
	System	01 Sep 2020 04:07:15

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:06', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2eb8bf12-0bed-41be-857a-9722355bdc96' User entered 'None (1)'	System	01 Sep 2020 04:07:15
	System	01 Sep 2020 04:07:15

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2eb8bf12-0bed-41be-857a-9722355bdc96' User entered '01 Sep 2020 00:07'	System	01 Sep 2020 04:07:15
	System	01 Sep 2020 04:07:15

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 7'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89ed52d5-d8fb-4b4b-be3f-be2ed2a626f4'	System	02 Sep 2020 05:22:11
User entered 'None (1)'	System	02 Sep 2020 05:22:11

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:21:58', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89ed52d5-d8fb-4b4b-be3f-be2ed2a626f4' User entered 'No (N)'	System	02 Sep 2020 05:22:11
	System	02 Sep 2020 05:22:11

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:02', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89ed52d5-d8fb-4b4b-be3f-be2ed2a626f4'	System	02 Sep 2020 05:22:11
User entered 'No (N)'	System	02 Sep 2020 05:22:11

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:06', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89ed52d5-d8fb-4b4b-be3f-be2ed2a626f4'	System	02 Sep 2020 05:22:11
User entered 'None (1)'	System	02 Sep 2020 05:22:11

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '89ed52d5-d8fb-4b4b-be3f-be2ed2a626f4' User entered '02 Sep 2020 01:22'	System	02 Sep 2020 05:22:11
	System	02 Sep 2020 05:22:11

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered 'None (0)'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7'	System	26 Aug 2020 16:24:50
User entered 'No (N)'	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T12:24:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd074410d-f488-4b76-90ee-3907a2725fd7' User entered '26 Aug 2020 12:24'	System	26 Aug 2020 16:24:50
	System	26 Aug 2020 16:24:50

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 14:32'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:43:53', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c'	System	27 Aug 2020 02:44:41
User entered 'No interference with activity (1)'	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c'	System	27 Aug 2020 02:44:41
User entered 'No interference with activity (1)'	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:04', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered 'None (0)'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered 'None (0)'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:16', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered 'None (0)'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered 'None (0)'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered 'No (N)'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-26T22:44:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b69031d2-b269-4688-b20a-9a0a0a54a37c' User entered '26 Aug 2020 22:44'	System	27 Aug 2020 02:44:41
	System	27 Aug 2020 02:44:41

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '26 Aug 2020 15:27'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 2'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f'	System	28 Aug 2020 10:01:16
User entered 'No interference with activity (1)'	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f'	System	28 Aug 2020 10:01:16
User entered 'No interference with activity (1)'	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:55', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered 'None (0)'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:00:59', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered 'None (0)'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:01:04', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered 'None (0)'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:01:07', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered 'None (0)'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:01:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered 'No (N)'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T06:01:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f9603baa-8c96-488c-adbc-9395ec72da0f' User entered '28 Aug 2020 06:01'	System	28 Aug 2020 10:01:16
	System	28 Aug 2020 10:01:16

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 3'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'None (0)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:38', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74'	System	29 Aug 2020 02:34:02
User entered 'No interference with activity (1)'	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:42', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'None (0)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'None (0)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'None (0)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:52', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'None (0)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:33:57', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered 'No (N)'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-28T22:34:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '95ee5eb8-e9bb-4d09-ac15-50974f3a6d74' User entered '28 Aug 2020 22:34'	System	29 Aug 2020 02:34:02
	System	29 Aug 2020 02:34:02

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 4'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:37:56', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62' User entered 'None (0)'	System	29 Aug 2020 22:38:27
	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:03', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62'	System	29 Aug 2020 22:38:27
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:06', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62' User entered 'None (0)'	System	29 Aug 2020 22:38:27
	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62' User entered 'None (0)'	System	29 Aug 2020 22:38:27
	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:13', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62' User entered 'None (0)'	System	29 Aug 2020 22:38:27
	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:16', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62' User entered 'None (0)'	System	29 Aug 2020 22:38:27
	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62'	System	29 Aug 2020 22:38:27
User entered 'No (N)'	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-29T18:38:24', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8d019ad3-4088-4f6d-a8f9-fc2a296cef62'	System	29 Aug 2020 22:38:27
User entered '29 Aug 2020 18:38'	System	29 Aug 2020 22:38:27

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 5'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:49', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:55', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:55:58', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:56:02', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:56:05', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'None (0)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:56:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered 'No (N)'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-08-31T05:56:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '189e9108-66d3-4182-ae46-b90d253a6555'	System	31 Aug 2020 09:56:14
User entered '31 Aug 2020 05:56'	System	31 Aug 2020 09:56:14

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 6'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:15', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:38', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'None (0)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered 'No (N)'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-01T00:07:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '285be8db-53a7-4738-87fb-b0b20da84d51' User entered '01 Sep 2020 00:07'	System	01 Sep 2020 04:07:52
	System	01 Sep 2020 04:07:52

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	26 Aug 2020 16:15:57
User entered 'Day 7'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:16', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'None (0)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'None (0)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:21', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcffe'	System	02 Sep 2020 05:22:43
User entered 'None (0)'	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:26', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'None (0)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:29', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'None (0)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'None (0)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:35', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered 'No (N)'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-02T01:22:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '2ad547b2-0910-4adf-8f09-d1eeaefcfcfd' User entered '02 Sep 2020 01:22'	System	02 Sep 2020 05:22:43
	System	02 Sep 2020 05:22:43

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:15:57

US3052044

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:15:57

US3052044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:58:35

US3052044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 09:21:58
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'the date is correct as entered' (Site from System).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:01:44
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 17:58:35
User entered '14 Sep 2020'	Avia McClain-Stocker (b) (4)	01 Oct 2020 17:58:35

US3052044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:58:35

US3052044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:58:35

US3052044

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:41:16

US3052044

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	30 Sep 2020 14:41:16

US3052044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:00:18

US3052044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 09:29:42
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'the date is correct as entered' (Site from System).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:02:01
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 18:00:18
User entered '21 Sep 2020'	Avia McClain-Stocker (b) (4)	01 Oct 2020 18:00:18

US3052044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:00:18

US3052044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 18:00:18

US3052044

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:41:28

US3052044

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	30 Sep 2020 14:41:28

US3052044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:59:46

US3052044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 09:22:06
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'the date is correct as entered' (Site from System).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:02:26
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 17:59:46
User entered '28 Sep 2020'	Avia McClain-Stocker (b) (4)	01 Oct 2020 17:59:46

US3052044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:59:46

US3052044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Oct 2020 17:59:46

US3052044

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4)	
	Stacey Saldua (b) (4)	30 Sep 2020 14:41:40
	(b) (4)	

US3052044

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	30 Sep 2020 14:41:40

US3052044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:42:13

US3052044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:42:13

US3052044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:42:13

US3052044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'VISIT3'	System	30 Sep 2020 14:42:13

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '14:43'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '29 Sep 2020 14:43'	System	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '98.6' F	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '54'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'bpm'	System	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '14'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'breaths/min'	System	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User closed query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	(b) (4) (b) (4), (b) (6)	08 Mar 2021 06:50:58
' (Site from DM).		
Query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	(b) (4), (b) (6)	05 Mar 2021 18:21:27
' answered with 'NCS' (Site from DM).		
User opened query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	(b) (4), (b) (6)	21 Oct 2020 08:51:24
' (Site from DM).		
User entered '171'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered '81'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'mmHg'	System	30 Sep 2020 14:45:41

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15

US3052044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15

US3052044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:46:31

US3052044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:46:31

US3052044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:47:27

US3052044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:47:27

US3052044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15:25'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:47:27

US3052044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
User entered '29 Sep 2020 15:25'	System	30 Sep 2020 14:47:27

US3052044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 14:47:44

US3052044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User entered 'I'	System	30 Sep 2020 14:47:44

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 64'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-30T00:01:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e01d592d-4e9b-4c3f-80fb-5df2695e0ad2'	System	30 Sep 2020 04:02:14
User entered 'No (N)'	System	30 Sep 2020 04:02:14

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-30T00:01:54', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e01d592d-4e9b-4c3f-80fb-5df2695e0ad2'	System	30 Sep 2020 04:02:14
User entered 'No (N)'	System	30 Sep 2020 04:02:14

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-09-30T00:02:09', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'e01d592d-4e9b-4c3f-80fb-5df2695e0ad2' User entered '30 Sep 2020 00:02:09'	System	30 Sep 2020 04:02:14
	System	30 Sep 2020 04:02:14

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 71'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:56:06
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 78'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-17T17:59:28', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1722bcd7-8660-4a38-a511-1117a395ef16'	System	17 Oct 2020 22:00:05
User entered 'No (N)'	System	17 Oct 2020 22:00:05

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-17T17:59:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1722bcd7-8660-4a38-a511-1117a395ef16'	System	17 Oct 2020 22:00:05
User entered 'No (N)'	System	17 Oct 2020 22:00:05

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-17T17:59:58', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1722bcd7-8660-4a38-a511-1117a395ef16' User entered '17 Oct 2020 17:59:58'	System	17 Oct 2020 22:00:05
	System	17 Oct 2020 22:00:05

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 92'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-31T10:00:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '250299a5-74ea-45de-abcb-928db6e3514a' User entered 'No (N)'	System	31 Oct 2020 14:00:30
	System	31 Oct 2020 14:00:30

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-31T10:00:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '250299a5-74ea-45de-abcb-928db6e3514a'	System	31 Oct 2020 14:00:30
User entered 'No (N)'	System	31 Oct 2020 14:00:30

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-10-31T10:00:28', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '250299a5-74ea-45de-abcb-928db6e3514a' User entered '31 Oct 2020 10:00:28'	System	31 Oct 2020 14:00:30
	System	31 Oct 2020 14:00:30

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 99'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-04T00:01:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a566d39c-4b88-454a-be1f-66e43a0c782e' User entered 'No (N)'	System	04 Nov 2020 05:02:19
	System	04 Nov 2020 05:02:19

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-04T00:02:02', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a566d39c-4b88-454a-be1f-66e43a0c782e'	System	04 Nov 2020 05:02:19
User entered 'No (N)'	System	04 Nov 2020 05:02:19

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-04T00:02:08', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a566d39c-4b88-454a-be1f-66e43a0c782e' User entered '04 Nov 2020 00:02:08'	System	04 Nov 2020 05:02:19
	System	04 Nov 2020 05:02:19

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 106'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-11T00:01:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e2aa9c0-3dce-414e-90d8-cd3454211c2f' User entered 'No (N)'	System	11 Nov 2020 05:01:56
	System	11 Nov 2020 05:01:56

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-11T00:01:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e2aa9c0-3dce-414e-90d8-cd3454211c2f' User entered 'No (N)'	System	11 Nov 2020 05:01:56
	System	11 Nov 2020 05:01:56

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-11T00:01:49', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '0e2aa9c0-3dce-414e-90d8-cd3454211c2f' User entered '11 Nov 2020 00:01:49'	System	11 Nov 2020 05:01:56
	System	11 Nov 2020 05:01:56

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered 'Day 113'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-18T18:08:26', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd004c3a8-21d1-45e4-8b65-af84e32586b3'	System	18 Nov 2020 23:08:45
User entered 'No (N)'	System	18 Nov 2020 23:08:45

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-18T18:08:36', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd004c3a8-21d1-45e4-8b65-af84e32586b3'	System	18 Nov 2020 23:08:45
User entered 'No (N)'	System	18 Nov 2020 23:08:45

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-18T18:08:43', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd004c3a8-21d1-45e4-8b65-af84e32586b3' User entered '18 Nov 2020 18:08:43'	System	18 Nov 2020 23:08:45
	System	18 Nov 2020 23:08:45

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 16:18:03

US3052044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:09:55
Data entry locked.	System	31 Jul 2020 16:18:03
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 16:18:03

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-30T12:05:42', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '67b845a7-69cf-4a9b-b37c-a39821d94494'	System	30 Nov 2020 17:05:55
User entered 'No (N)'	System	30 Nov 2020 17:05:55

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-30T12:05:47', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '67b845a7-69cf-4a9b-b37c-a39821d94494'	System	30 Nov 2020 17:05:55
User entered 'No (N)'	System	30 Nov 2020 17:05:55

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-11-30T12:05:51', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '67b845a7-69cf-4a9b-b37c-a39821d94494' User entered '30 Nov 2020 12:05:51'	System	30 Nov 2020 17:05:55
	System	30 Nov 2020 17:05:55

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? 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)	16 Mar 2021 14:23:55
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? 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 indication per source that the subject spoke with the site about this entry' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 18:36:33
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? 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)	26 Feb 2021 08:56:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:53:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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)
User entered 'Yes (Y)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:53:49', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered 'No (N)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:03', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered 'Yes (Y)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '1'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '1'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '1'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '1'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46
	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46
	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46
	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46
	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '1'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:54:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '0'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Please 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:55:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:55:10', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered 'Yes (Y)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Please 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:55:24', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607'	System	06 Dec 2020 14:55:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-06T09:55:37', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a6ad8dee-d5fc-4815-82b8-fd575a5a6607' User entered '06 Dec 2020 09:55:37'	System	06 Dec 2020 14:55:46
	System	06 Dec 2020 14:55:46

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-16T05:52:32', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '6d56caa5-83c1-4b9f-ab43-ca8e572c04da' User entered 'No (N)'	System	16 Dec 2020 10:52:49
	System	16 Dec 2020 10:52:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-16T05:52:39', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '6d56caa5-83c1-4b9f-ab43-ca8e572c04da' User entered 'No (N)'	System	16 Dec 2020 10:52:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-16T05:52:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '6d56caa5-83c1-4b9f-ab43-ca8e572c04da' User entered '16 Dec 2020 05:52:45'	System	16 Dec 2020 10:52:49
	System	16 Dec 2020 10:52:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-20T00:01:34', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7c576123-07f3-4a04-9da2-f671a1460d21' User entered 'No (N)'	System	20 Dec 2020 05:02:00
	System	20 Dec 2020 05:02:00

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-20T00:01:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7c576123-07f3-4a04-9da2-f671a1460d21' User entered 'No (N)'	System	20 Dec 2020 05:02:00
	System	20 Dec 2020 05:02:00

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-20T00:01:46', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '7c576123-07f3-4a04-9da2-f671a1460d21' User entered '20 Dec 2020 00:01:46'	System	20 Dec 2020 05:02:00
	System	20 Dec 2020 05:02:00

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-28T15:06:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3b47a432-2849-4b4e-8c4e-15f3dc983194' User entered 'No (N)'	System	28 Dec 2020 20:06:44
	System	28 Dec 2020 20:06:44

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-28T15:06:31', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3b47a432-2849-4b4e-8c4e-15f3dc983194'	System	28 Dec 2020 20:06:44
User entered 'No (N)'	System	28 Dec 2020 20:06:44

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2020-12-28T15:06:41', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '3b47a432-2849-4b4e-8c4e-15f3dc983194' User entered '28 Dec 2020 15:06:41'	System	28 Dec 2020 20:06:44
	System	28 Dec 2020 20:06:44

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-03T16:07:07', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c22f3d28-4e30-4a0d-b7c1-f7b9225276dd' User entered 'No (N)'	System	03 Jan 2021 21:07:23
	System	03 Jan 2021 21:07:23

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-03T16:07:14', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c22f3d28-4e30-4a0d-b7c1-f7b9225276dd' User entered 'No (N)'	System	03 Jan 2021 21:07:23

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-03T16:07:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'c22f3d28-4e30-4a0d-b7c1-f7b9225276dd' User entered '03 Jan 2021 16:07:18'	System	03 Jan 2021 21:07:23

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-10T00:02:20', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '698c9e7c-cb66-45ab-af46-36702ad67820'	System	10 Jan 2021 05:03:29
User entered 'No (N)'	System	10 Jan 2021 05:03:29

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-10T00:02:23', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '698c9e7c-cb66-45ab-af46-36702ad67820'	System	10 Jan 2021 05:03:29
User entered 'No (N)'	System	10 Jan 2021 05:03:29

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-10T00:02:27', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '698c9e7c-cb66-45ab-af46-36702ad67820' User entered '10 Jan 2021 00:02:27'	System	10 Jan 2021 05:03:29

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:57:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'Yes (Y)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:57:52', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'No (N)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'Yes (Y)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '1'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '1'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '1'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '0'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:11', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered '0'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Please 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:19', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:33', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'Yes (Y)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Please 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03'	System	19 Jan 2021 14:58:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-19T09:58:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'd0953ca9-305b-44cc-9f32-36da4da6aa03' User entered '19 Jan 2021 09:58:48'	System	19 Jan 2021 14:58:58
	System	19 Jan 2021 14:58:58

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-25T00:31:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cfb329d1-4b5a-4cf9-93a0-a4cfd9ecfc05'	System	25 Jan 2021 05:31:53
User entered 'No (N)'	System	25 Jan 2021 05:31:53

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-25T00:31:45', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cfb329d1-4b5a-4cf9-93a0-a4cfd9ecfc05'	System	25 Jan 2021 05:31:53
User entered 'No (N)'	System	25 Jan 2021 05:31:53

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-25T00:31:50', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cfb329d1-4b5a-4cf9-93a0-a4cfd9ecfc05' User entered '25 Jan 2021 00:31:50'	System	25 Jan 2021 05:31:53

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-31T03:27:40', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9a4c4c5e-7630-4ad8-9885-b3c5cbcb2c2'	System	31 Jan 2021 08:27:50
User entered 'No (N)'	System	31 Jan 2021 08:27:50

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-31T03:27:44', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9a4c4c5e-7630-4ad8-9885-b3c5cbcb2c2'	System	31 Jan 2021 08:27:50
User entered 'No (N)'	System	31 Jan 2021 08:27:50

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-01-31T03:27:48', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '9a4c4c5e-7630-4ad8-9885-b3c5cbcb2c2' User entered '31 Jan 2021 03:27:48'	System	31 Jan 2021 08:27:50
	System	31 Jan 2021 08:27:50

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-09T12:19:12', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cba6e92d-6145-46ea-bdd6-efd4af3907e5'	System	09 Feb 2021 17:20:22
User entered 'No (N)'	System	09 Feb 2021 17:20:22

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-09T12:19:18', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cba6e92d-6145-46ea-bdd6-efd4af3907e5'	System	09 Feb 2021 17:20:22
User entered 'No (N)'	System	09 Feb 2021 17:20:22

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-09T12:19:22', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'cba6e92d-6145-46ea-bdd6-efd4af3907e5' User entered '09 Feb 2021 12:19:22'	System	09 Feb 2021 17:20:22
	System	09 Feb 2021 17:20:22

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-15T20:06:17', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8ff5a2bd-2228-42b9-b6d4-8b076aa60b2b' User entered 'No (N)'	System	16 Feb 2021 01:06:49
	System	16 Feb 2021 01:06:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-15T20:06:24', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8ff5a2bd-2228-42b9-b6d4-8b076aa60b2b' User entered 'No (N)'	System	16 Feb 2021 01:06:49
	System	16 Feb 2021 01:06:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-15T20:06:29', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '8ff5a2bd-2228-42b9-b6d4-8b076aa60b2b' User entered '15 Feb 2021 20:06:29'	System	16 Feb 2021 01:06:49
	System	16 Feb 2021 01:06:49

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-24T11:05:05-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '626ae388-8210-45b8-a197-29aa4e5428b6'	System	24 Feb 2021 16:05:17
User entered 'No (N)'	System	24 Feb 2021 16:05:17

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-24T11:05:08-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '626ae388-8210-45b8-a197-29aa4e5428b6'	System	24 Feb 2021 16:05:17
User entered 'No (N)'	System	24 Feb 2021 16:05:17

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-24T11:05:12-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '626ae388-8210-45b8-a197-29aa4e5428b6'	System	24 Feb 2021 16:05:17
User entered '24 Feb 2021 16:05:12'	System	24 Feb 2021 16:05:17

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-28T03:53:25-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ec386ef0-98c2-4bc3-898c-044c4f91c092'	System	28 Feb 2021 08:53:39
User entered 'No (N)'	System	28 Feb 2021 08:53:39

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-28T03:53:33-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ec386ef0-98c2-4bc3-898c-044c4f91c092'	System	28 Feb 2021 08:53:39
User entered 'No (N)'	System	28 Feb 2021 08:53:39

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-28T03:53:37-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'ec386ef0-98c2-4bc3-898c-044c4f91c092'	System	28 Feb 2021 08:53:39
User entered '28 Feb 2021 08:53:37'	System	28 Feb 2021 08:53:39

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-08T16:37:00-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f8672049-4846-4093-94b0-6ad87f2c8699'	System	08 Mar 2021 21:37:11
User entered 'No (N)'	System	08 Mar 2021 21:37:11

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-08T16:37:03-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f8672049-4846-4093-94b0-6ad87f2c8699'	System	08 Mar 2021 21:37:11
User entered 'No (N)'	System	08 Mar 2021 21:37:11

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-08T16:37:06-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f8672049-4846-4093-94b0-6ad87f2c8699'	System	08 Mar 2021 21:37:11
User entered '08 Mar 2021 16:37:06'	System	08 Mar 2021 21:37:11

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-16T12:51:53-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f33a3135-19b8-4012-922a-eb60ef34bf97'	System	16 Mar 2021 16:52:04
User entered 'No (N)'	System	16 Mar 2021 16:52:04

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-16T12:51:55-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f33a3135-19b8-4012-922a-eb60ef34bf97'	System	16 Mar 2021 16:52:04
User entered 'No (N)'	System	16 Mar 2021 16:52:04

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-16T12:52:00-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f33a3135-19b8-4012-922a-eb60ef34bf97'	System	16 Mar 2021 16:52:04
User entered '16 Mar 2021 12:52:00'	System	16 Mar 2021 16:52:04

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-21T11:34:06-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f13bd07d-e8c9-4c9b-b31d-92300021e975'	System	21 Mar 2021 15:34:16
User entered 'No (N)'	System	21 Mar 2021 15:34:16

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-21T11:34:09-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f13bd07d-e8c9-4c9b-b31d-92300021e975'	System	21 Mar 2021 15:34:16
User entered 'No (N)'	System	21 Mar 2021 15:34:16

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-21T11:34:13-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'f13bd07d-e8c9-4c9b-b31d-92300021e975'	System	21 Mar 2021 15:34:16
User entered '21 Mar 2021 11:34:13'	System	21 Mar 2021 15:34:16

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-30T12:06:57-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b5ec9658-7cfe-4939-8eed-c292e116ec0d'	System	30 Mar 2021 16:13:54
User entered 'No (N)'	System	30 Mar 2021 16:13:54

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-30T12:07:00-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b5ec9658-7cfe-4939-8eed-c292e116ec0d'	System	30 Mar 2021 16:13:54
User entered 'No (N)'	System	30 Mar 2021 16:13:54

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-03-30T12:07:04-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'b5ec9658-7cfe-4939-8eed-c292e116ec0d' User entered '30 Mar 2021 12:07:04'	System	30 Mar 2021 16:13:54
	System	30 Mar 2021 16:13:54

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-07T15:08:52-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '10647e43-082a-4d3c-886a-63635331bb0e' User entered 'No (N)'	System	07 Apr 2021 19:09:05
	System	07 Apr 2021 19:09:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-07T15:08:54-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '10647e43-082a-4d3c-886a-63635331bb0e' User entered 'No (N)'	System	07 Apr 2021 19:09:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-07T15:08:58-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '10647e43-082a-4d3c-886a-63635331bb0e'	System	07 Apr 2021 19:09:05
User entered '07 Apr 2021 15:08:58'	System	07 Apr 2021 19:09:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-11T21:32:55-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a447a6e3-1154-49c9-8a1e-513b72d37052'	System	12 Apr 2021 01:33:06
User entered 'No (N)'	System	12 Apr 2021 01:33:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-11T21:32:58-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a447a6e3-1154-49c9-8a1e-513b72d37052'	System	12 Apr 2021 01:33:06
User entered 'No (N)'	System	12 Apr 2021 01:33:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-11T21:33:01-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'a447a6e3-1154-49c9-8a1e-513b72d37052'	System	12 Apr 2021 01:33:06
User entered '11 Apr 2021 21:33:01'	System	12 Apr 2021 01:33:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-20T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b346ad1-899a-443a-a3ec-cc59d4d31f92'	System	20 Apr 2021 16:00:47
User entered 'No (N)'	System	20 Apr 2021 16:00:47

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-20T12:00:22-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b346ad1-899a-443a-a3ec-cc59d4d31f92'	System	20 Apr 2021 16:00:47
User entered 'No (N)'	System	20 Apr 2021 16:00:47

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-20T12:00:26-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b346ad1-899a-443a-a3ec-cc59d4d31f92'	System	20 Apr 2021 16:00:47
User entered '20 Apr 2021 12:00:26'	System	20 Apr 2021 16:00:47

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-25T07:36:51-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b73fabc-16a4-423f-9858-956e1831e934'	System	25 Apr 2021 11:37:01
User entered 'No (N)'	System	25 Apr 2021 11:37:01

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-25T07:36:54-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b73fabc-16a4-423f-9858-956e1831e934'	System	25 Apr 2021 11:37:01
User entered 'No (N)'	System	25 Apr 2021 11:37:01

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-04-25T07:36:59-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '1b73fabc-16a4-423f-9858-956e1831e934'	System	25 Apr 2021 11:37:01
User entered '25 Apr 2021 07:36:59'	System	25 Apr 2021 11:37:01

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-05-02T06:30:54-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '768242d5-8404-4575-86c0-61c937c4ccef'	System	02 May 2021 10:31:05
User entered 'No (N)'	System	02 May 2021 10:31:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

Have you been exposed to someone with 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 (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-05-02T06:30:58-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '768242d5-8404-4575-86c0-61c937c4ccef'	System	02 May 2021 10:31:05
User entered 'No (N)'	System	02 May 2021 10:31:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-05-02T06:31:01-04:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: '768242d5-8404-4575-86c0-61c937c4cccf'	System	02 May 2021 10:31:05
User entered '02 May 2021 06:31:01'	System	02 May 2021 10:31:05

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 10:56:06

US3052044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:56:06
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 10:56:06

US3052044

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:55:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-28T03:53:00-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'edf9fd32-3c7d-4fc6-b74c-d6c690db0594'	System	28 Feb 2021 08:53:20
User entered 'No (N)'	System	28 Feb 2021 08:53:20

US3052044

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:55:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:41:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5CF43C-E4EA-4000-8B27-EECFBFC51673)', Time: '2021-02-28T03:53:18-05:00', User OID: 'PatientReportedOutcome (US3052044)', ODM File OID: 'edf9fd32-3c7d-4fc6-b74c-d6c690db0594'	System	28 Feb 2021 08:53:20
User entered '28 Feb 2021 08:53:18'	System	28 Feb 2021 08:53:20

US3052044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	21 Oct 2020 12:30:42

US3052044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '20 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	21 Oct 2020 12:30:42

US3052044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	21 Oct 2020 12:30:42

US3052044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	21 Oct 2020 12:30:42

US3052044

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.		03 Apr 2021 20:53:15
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Dec 2020 21:12:15

US3052044

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:24:06
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:53:15
User entered 'I'	System	14 Dec 2020 21:12:15

US3052044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Dec 2020 20:23:46

US3052044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '27 Nov 2020'	amy sheets (b) (4)	31 Dec 2020 20:23:46

US3052044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) amy sheets (b) (4) (b) (4)	31 Dec 2020 20:23:46

US3052044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	amy sheets (b) (4)	31 Dec 2020 20:23:46

US3052044

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Dec 2020 21:12:23

US3052044

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'I'	System	14 Dec 2020 21:12:23

US3052044

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	04 Jan 2021 14:56:55

US3052044

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '27 Dec 2020'	Avia McClain-Stocker (b) (4)	04 Jan 2021 14:56:55

US3052044

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	Avia McClain-Stocker (b) (4)	04 Jan 2021 14:56:55

US3052044

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'leftVM'	Avia McClain-Stocker (b) (4)	04 Jan 2021 14:56:55

US3052044

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	04 Jan 2021 14:56:59

US3052044

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'I'	System	04 Jan 2021 14:56:59

US3052044

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:38:49

US3052044

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:49:30
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct ' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 14:39:02
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 14:38:49
User entered '30 Jan 2021'	(b) (4), (b) (6)	12 Mar 2021 14:38:49

US3052044

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:38:49

US3052044

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:38:49

US3052044

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:24

US3052044

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'I'	System	25 Mar 2021 18:37:24

US3052044

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:35

US3052044

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 15:22:28
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Confirmed date' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:49
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Mar 2021 18:37:35
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 18:37:35

US3052044

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:35

US3052044

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'VISIT4'	System	25 Mar 2021 18:37:35

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '08:46'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered '18 Mar 2021 08:46'	System	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 20:58:43
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not clinical significant' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:39:33
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	31 Mar 2021 12:38:58
User entered '96.5' F	(b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '58'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'bpm'	System	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '12'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'breaths/min'	System	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '147'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'mmHg'	System	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '84'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'mmHg'	System	31 Mar 2021 12:38:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04

US3052044

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04

US3052044

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:58

US3052044

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:19

US3052044

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:19

US3052044

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '09:05'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:19

US3052044

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered '18 Mar 2021 09:05'	System	25 Mar 2021 18:38:19

US3052044

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:02

US3052044

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:07:04
User entered 'I'	System	26 Mar 2021 20:32:02

US3052044

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:18

US3052044

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:18

US3052044

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:18

US3052044

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:18

US3052044

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:25:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:32:26

US3052044

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:37
User entered 'I'	System	26 Mar 2021 20:32:26

US3052044

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:26:38
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 15:34:42

US3052044

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 18:39:24
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:26:38
Query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SAFETY CALL CONDUCTED OUT OF WINDOW IN ERROR' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:34:47
User opened query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Apr 2021 15:34:42
User entered '27 Apr 2021'	(b) (4), (b) (6)	27 Apr 2021 15:34:42

US3052044

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:26:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:34:42

US3052044

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:26:38
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 15:34:42

US3052044

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:26:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:34:51

US3052044

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 15:34:51

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:27
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10 Aug 2020'	amy sheets (b) (4)	18 Aug 2020 19:10:43

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:27
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '18:57'	amy sheets (b) (4)	18 Aug 2020 19:10:43

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:27
User entered '10 Aug 2020 18:57'	System	18 Aug 2020 19:10:43

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:27
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Safety Call (Safety Call)'	amy sheets (b) (4)	18 Aug 2020 19:10:43

US3052044

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:27
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 19:10:43

US3052044

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:26:31

US3052044

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:26:31

US3052044

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:26:31

US3052044

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 13:26:31

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:39:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:08:41

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:39:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:08:41

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:00:17
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:00:17
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '1'	System	19 Jan 2021 13:27:00

US3052044

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'I'	System	19 Jan 2021 13:27:00

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '173' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '91' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '30.40529'	System	19 Jan 2021 13:30:35
DataPoint set to visible.	System	19 Jan 2021 13:27:00

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '173' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '91' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '30.40529'	System	19 Jan 2021 13:30:35
DataPoint set to visible.	System	19 Jan 2021 13:27:00

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User accepted default value 'Pre-Dose (PREDOSE)'		19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '11:49'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Jan 2021 11:49'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '67'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'bpm'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'breaths/min'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '149'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '86'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '173' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '91' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '30.40529'	System	19 Jan 2021 13:30:35
DataPoint set to visible.	System	19 Jan 2021 13:27:00

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User accepted default value 'Post-Dose (POSTDOSE)'		19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12:59'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Jan 2021 12:59'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '62'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'bpm'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'breaths/min'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '144'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '83'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:30:35

US3052044

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	19 Jan 2021 13:30:35

US3052044

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:06

US3052044

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:06

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

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)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mRNA-1273'	System	19 Jan 2021 13:31:35
DataPoint set to visible.	System	19 Jan 2021 13:27:00

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12:26'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Jan 2021 12:26'	System	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'ONCE'	System	19 Jan 2021 13:31:35

US3052044

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

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 13:31:35

US3052044

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:04

US3052044

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:04

US3052044

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12:20'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:04

US3052044

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Jan 2021 12:20'	System	19 Jan 2021 13:32:04

US3052044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:50

US3052044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:50

US3052044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12:23'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:50

US3052044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Jan 2021 12:23'	System	19 Jan 2021 13:32:50

US3052044

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

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:32:58

US3052044

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

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '1'	System	19 Jan 2021 13:32:58

US3052044

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:51

US3052044

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		16 Mar 2021 15:39:43
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct ' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:40:41
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 14:39:51
User entered '30 Jan 2021'	(b) (4), (b) (6)	12 Mar 2021 14:39:51

US3052044

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:51

US3052044

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:51

US3052044

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:56:25

US3052044

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'I'	System	16 Feb 2021 14:56:25

US3052044

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '1'	System	16 Feb 2021 14:56:25
DataPoint set to visible.	System	16 Feb 2021 14:56:25

US3052044

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:56:46

US3052044

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:56:46

US3052044

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:56:46

US3052044

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'OLD29'	System	16 Feb 2021 14:56:46

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User accepted default value 'Pre-Dose (PREDOSE)'		16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '09:25'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Feb 2021 09:25'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '68'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'bpm'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'breaths/min'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '118'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '68'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '10:38'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Feb 2021 10:38'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '64'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'bpm'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '12'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'breaths/min'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '115'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '74'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	16 Feb 2021 14:59:03

US3052044

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:17

US3052044

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:17

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

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)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mRNA-1273'	System	16 Feb 2021 14:59:42
DataPoint set to visible.	System	16 Feb 2021 14:56:25

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered '09:47'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '15 Feb 2021 09:47'	System	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'ONCE'	System	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 14:59:42

US3052044

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:00:09

US3052044

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'I'	System	16 Feb 2021 15:00:09

US3052044

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Mar 2021 19:10:32
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Mar 2021 14:41:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 14:41:06

US3052044

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:41:06

US3052044

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered empty; reason for change Data Entry Error	amy sheets (b) (4)	12 Mar 2021 19:10:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	12 Mar 2021 14:41:06

US3052044

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'missed'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:41:06

US3052044

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 15:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:41:15

US3052044

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'I'	System	12 Mar 2021 14:41:15

US3052044

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:35:40

US3052044

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:35:40

US3052044

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:35:40

US3052044

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'OLD57'	System	25 Mar 2021 18:35:40

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 18:36:38
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Mar 2021 18:36:38
User entered '08:46' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:36:38
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Mar 2021 18:36:23
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '18 Mar 2021 08:46'	System	25 Mar 2021 18:36:38
User entered empty.	System	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		29 Mar 2021 15:22:04
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not clinically significant' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:37:01
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Mar 2021 18:36:23
User entered '96.5' F	(b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '58'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'bpm'	System	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '12'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'breaths/min'	System	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '147'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '84'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered 'mmHg'	System	25 Mar 2021 18:36:23

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08

US3052044

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08

US3052044

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:35

US3052044

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:35

US3052044

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:52

US3052044

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:52

US3052044

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '09:05'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:38:52

US3052044

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:42:08
User entered '18 Mar 2021 09:05'	System	25 Mar 2021 18:38:52

US3052044

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:55:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:43:36
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:29:51
User closed query 'Per CDM, DM CLR RQ: Please note that Safety Follow Up Diary Day 173 entry was on 19 Jan 2021 and there are no new AEs recorded close to that date. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Apr 2021 12:52:39
Query 'Per CDM, DM CLR RQ: Please note that Safety Follow Up Diary Day 173 entry was on 19 Jan 2021 and there are no new AEs recorded close to that date. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'no changes reported ' (Site from DM).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:44:14
User opened query 'Per CDM, DM CLR RQ: Please note that Safety Follow Up Diary Day 173 entry was on 19 Jan 2021 and there are no new AEs recorded close to that date. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:52:22
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 173, '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)	15 Apr 2021 12:52:22

US3052044

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:55:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR re-query on New Safety Follow Up Diary, Day 131: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Site response indicates "no indication per source that the subject spoke with the site about this entry". At the next patient contact, please review if a Medically-attended AE should be recorded, otherwise provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:49:50
Query 'Per DM CLR: Per Safety Follow Up Diary Day 173, '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 'UPDATED SOURCE' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:07:09
Query 'Per CDM, DM CLR re-query on New Safety Follow Up Diary, Day 131: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Site response indicates "no indication per source that the subject spoke with the site about this entry". At the next patient contact, please review if a Medically-attended AE should be recorded, otherwise provide clarification. Thank you. ' answered with 'UPDATED SOURCE' (Site from DM).		12 Apr 2021 15:07:02
Signature has been broken.		12 Apr 2021 15:06:56
User entered 'Yes (Y)' reason for change: Data Entry Error		12 Apr 2021 15:06:56

US3052044

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:55:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 173, '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)	25 Mar 2021 00:56:10
User opened query 'Per CDM, DM CLR re-query on New Safety Follow Up Diary, Day 131: Any changes since last questionnaire or contact with study clinic?; Experienced any new COVID-19 symptoms since last questionnaire or study contact? and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Site response indicates "no indication per source that the subject spoke with the site about this entry". At the next patient contact, please review if a Medically-attended AE should be recorded, otherwise provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:23:48
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:11:07

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:57:55
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered	(b) (4)	13 Apr 2021 17:44:58
'USA-US117-2021-mRNA-1273-P301000008'	System	13 Apr 2021 17:44:58
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 17:44:58

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 15:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 15:30:48
Data point term sent to Coder	System	12 Apr 2021 15:23:42
User entered 'COPD EXACERBATION'	(b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:18
User closed query 'PV Query: SAE form states that the event was medically significant and life-threatening (in addition to hospitalization), however eCRF solely lists hospitalization as a seriousness criteria; kindly update eCRF to match SAE form else clarify. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:57:42
Query 'PV Query: SAE form states that the event was medically significant and life-threatening (in addition to hospitalization), however eCRF solely lists hospitalization as a seriousness criteria; kindly update eCRF to match SAE form else clarify. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:09:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 16:09:26
User entered '1' reason for change: Data Entry Error		20 Apr 2021 16:09:26
User opened query 'PV Query: SAE form states that the event was medically significant and life-threatening (in addition to hospitalization), however eCRF solely lists hospitalization as a seriousness criteria; kindly update eCRF to match SAE form else clarify. ' (Site from Safety).		20 Apr 2021 12:54:55
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:18
User closed query 'PV Query: SAE form states that action taken was "none", but eCRF states "not applicable"; could you confirm that action taken was not applicable as the subject had received both scheduled doses? ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:57:44
Query 'PV Query: SAE form states that action taken was "none", but eCRF states "not applicable"; could you confirm that action taken was not applicable as the subject had received both scheduled doses? ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:10:00
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 16:09:26
User entered 'None (NONE)' reason for change: Data Entry Error		20 Apr 2021 16:09:26
User opened query 'PV Query: SAE form states that action taken was "none", but eCRF states "not applicable"; could you confirm that action taken was not applicable as the subject had received both scheduled doses? ' (Site from Safety).		20 Apr 2021 12:55:21
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm whether or not the subject had used albuterol prior to the start of the event (06 Dec 2020)? ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:57:46
Query 'PV Query: Please confirm whether or not the subject had used albuterol prior to the start of the event (06 Dec 2020)? ' answered with 'confirmed' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:11:12
User opened query 'PV Query: Please confirm whether or not the subject had used albuterol prior to the start of the event (06 Dec 2020)? ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:55:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:09:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:18:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'MEDICAL RECORDS HAVE BEEN REQUESTED AGAIN. WE DO NOT HAVE FURTHER INFORMATION.' (Site from Safety).	Jeanette Mangual-Coughlin (b) (4)	23 Apr 2021 16:01:14
User closed query 'PV Query: medical history states that subject suffered two rotator cuff injuries to his right shoulder in 2005; are these duplicated entries, or were they two separate incidents? ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:57:49
Query 'PV Query: medical history states that subject suffered two rotator cuff injuries to his right shoulder in 2005; are these duplicated entries, or were they two separate incidents? ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:42:12
User opened query 'PV Query: medical history states that subject suffered two rotator cuff injuries to his right shoulder in 2005; are these duplicated entries, or were they two separate incidents? ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:55:30

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 12:55:14
	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
	(b) (4)	
User entered 'SUBJECT REPORTED BEING ADMITTED TO THE HOSPITAL FOR A COPD EXACERBATION ON 06DEC2020.'	(b) (4), (b) (6)	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:22:43

US3052044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 15:22:43

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:55:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:43:36
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:11:51

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder User entered 'Losartan'	System amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:27 18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:21:43
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Reviewed and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	16 Nov 2020 20:25:26
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:01:22
User closed query 'Per CDM, per DM CLR re-query: Response noted; however, HYPERTENSION has not been added to the MH eCRF. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:05:26
Query 'Per CDM, per DM CLR re-query: Response noted; however, HYPERTENSION has not been added to the MH eCRF. Please update as appropriate.' answered with 'RESOLVED' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:22:53
User opened query 'Per CDM, per DM CLR re-query: Response noted; however, HYPERTENSION has not been added to the MH eCRF. Please update as appropriate.' (Site from DM).		19 Oct 2020 10:44:03
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		19 Oct 2020 10:44:03
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:54:19

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:14:38
User entered 'Hypertension'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '100'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:39:52
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	11 Oct 2020 15:32:02
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:54:13
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:15:06
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:12:37

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 23:26:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:31
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Plavix'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'History of CABG'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '75'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:13:14
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:40:41
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:54:43
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:54:37
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:39:48
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:13:14

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 23:34:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:34:40
Data point term sent to Coder	System	18 Aug 2020 19:14:31
User entered 'Aspirin'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'History of CABG'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '81'	amy sheets (b) (4)	18 Aug 2020 19:13:52
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:13:52
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:40:47
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:55:06
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:55:00
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:38:07
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:13:52

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 23:26:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:44
Data point term sent to Coder	System	18 Aug 2020 19:15:36
User entered 'Novolog'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:38:33
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:31
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:23
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:13:34
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Diabetes'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per CDM, per DM CLR re-query: Please update as appropriate to provide the scale dose. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:49:43
Query 'Per CDM, per DM CLR re-query: Please update as appropriate to provide the scale dose. Thank you. ' answered with '- Subject does a bolus: 2 units/hr - Sliding scale for glucose >120 = 1 unit/10 above 120 - Carb count 1 unit/10 carbs' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:50:32
User entered 'see note' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:50:28
User opened query 'Per CDM, per DM CLR re-query Please update as appropriate to provide the scale dose. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:55:39
User closed query 'Per DM CLR: Please review and provide the scale dose (e.g., 5-10 units). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:39:26
Query 'Per DM CLR: Please review and provide the scale dose (e.g., 5-10 units). Update as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:38
User entered '1' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:23
User opened query 'Per DM CLR: Please review and provide the scale dose (e.g., 5-10 units). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:25:18
User entered 'Sliding Scale'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Other (OTHER)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	10 Oct 2020 23:56:23
User entered 'sliding scale' reason for change: Data Entry Error	amy sheets (b) (4)	10 Oct 2020 23:56:23
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	18 Aug 2020 19:14:36
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:14:36
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'as needed (PRN)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:41:02
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:46
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:56:23
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:26:13
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 19:14:36

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:48:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:48:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 21:25:23 23 Oct 2020 21:25:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 23:58:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 23:58:29
Data point term sent to Coder Coding entries removed.	System amy sheets (b) (4)	10 Oct 2020 23:58:16 10 Oct 2020 23:57:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:26:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:26:35
Data point term sent to Coder User entered 'Atorvastatin'	System amy sheets (b) (4)	18 Aug 2020 19:15:38 18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) amy sheets (b) (4)	10 Oct 2020 23:57:32
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per CDM, per DM CLR re-query: Please note that the indication for this medication is not listed in the MH or AE eCRFs. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:10:19
Query 'Per CDM, per DM CLR re-query: Please note that the indication for this medication is not listed in the MH or AE eCRFs. Please update as appropriate. ' answered with 'subject stated that he does not have high cholesterol, but that this medication was prescribed in accordance with maintaining the positive effects of CABG' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:25:19
User entered 'HISTORY OF CABG' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:25:15
User opened query 'Per CDM, per DM CLR re-query Please note that the indication for this medication is not listed in the MH or AE eCRFs. Please update as appropriate. ' (Site from DM).		19 Oct 2020 10:36:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).		19 Oct 2020 10:36:49
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:57:39
User entered 'hypercholesterolemia' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:57:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 08:00:49
User entered 'Cholesterol'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '80'	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:15:23
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:35:10
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:15:23

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Oct 2020 12:44:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:44:36
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 21:26:24 23 Oct 2020 21:26:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:39
Data point term sent to Coder User entered 'Carvedilol'	System amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:42 18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:16:32
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:05:36
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'subject stated that he does not have hypertension, but that this medication was prescribed in accordance with maintaining the positive effects of CABG' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:26:08
User entered 'HISTORY OF CABG' reason for change: New Information		23 Oct 2020 21:26:04
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		09 Sep 2020 09:46:11
User entered 'Hypertension'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '6.25'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:16:32
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'twice daily (BID)'	amy sheets (b) (4)	18 Aug 2020 19:16:32
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:16:32
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:41:24
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:58:07
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:57:58
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:46:50
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:16:32

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
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)	25 Oct 2020 07:34:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 07:34:30
Data point term sent to Coder	System	23 Oct 2020 21:35:43
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 21:35:15
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.	Coder Import (b) (4)	11 Oct 2020 15:34:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Oct 2020 15:34:21
Data point term sent to Coder	System	11 Oct 2020 15:33:23
Coding entries removed.	amy sheets (b) (4)	11 Oct 2020 15:32:50
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.	Coder Import (b) (4)	18 Aug 2020 23:26:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:26:48
Data point term sent to Coder	System	18 Aug 2020 19:17:44
User entered 'Montelukast'	amy sheets (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 10:38:49
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:30:50
User entered 'No (N)' reason for change: Data Entry Error		05 Mar 2021 17:30:37
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		17 Dec 2020 01:38:20
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:02:35
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'subject is taking medication for sinusitis' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:35:23
User entered 'CHRONIC SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 21:35:15
User closed query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).		19 Oct 2020 10:34:05
Query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	11 Oct 2020 15:32:57
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	11 Oct 2020 15:32:50
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:44:49
User opened query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:44:20
User entered 'Allergies'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '10'	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:17:35
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:34:07
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:58:44
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 23:58:34
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:47:22
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:17:35

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE DINITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Oct 2020 08:11:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:11:30
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 22:16:17 23 Oct 2020 22:15:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE DINITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:55
Data point term sent to Coder User entered 'Isosorbide Dinitrate'	System amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:50 18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:05:59
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'med prescribed in association with cabg' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 22:16:02
User entered 'HISTORY OF CABG' reason for change: New Information		23 Oct 2020 22:15:57
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		09 Sep 2020 09:59:33
User entered 'Hypertension'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '20'	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'twice daily (BID)'	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:19:34
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:41:47
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:00:15
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:00:05
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:00:31
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:19:34

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:20
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:57
Data point term sent to Coder User entered 'Meclizine'	System amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:54 18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:41:59
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:01:14
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:01:04
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:14:08
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per CDM CLR re-query: Response noted; however, MH has not been updated. Kindly review and update the MH eCRF. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:14:34
Query 'Per CDM CLR re-query: Response noted; however, MH has not been updated. Kindly review and update the MH eCRF. Otherwise clarify. Thank you.' answered with 'updated MH' (Site from DM).	amy sheets (b) (4) (b) (4)	23 Mar 2021 17:52:39
User opened query 'Per CDM CLR re-query: Response noted; however, MH has not been updated. Kindly review and update the MH eCRF. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:47:19
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		11 Mar 2021 14:43:20
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH updated' (Site from DM).		05 Mar 2021 17:37:24
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		02 Nov 2020 12:07:10
User entered 'Vertigo'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '25'	amy sheets (b) (4)	18 Aug 2020 19:20:28
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:20:28
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:20:28
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	11 Oct 2020 00:01:04
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	18 Aug 2020 19:20:28
User entered 'three times daily (TID)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty; reason for change Data Entry	amy sheets (b) (4)	11 Oct 2020 00:01:04
Error	(b) (4)	
User entered 'PRN'	amy sheets (b) (4)	18 Aug 2020 19:20:28
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Oral (ORAL)'	amy sheets (b) (4)	18 Aug 2020 19:20:28
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:42:02
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:01:23
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	11 Oct 2020 00:01:04
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:17:43
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:20:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
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.	(b) (4) Coder Import (b) (4)	18 Aug 2020 23:27:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:27:02
Data point term sent to Coder	System	18 Aug 2020 19:21:55
User entered 'Albuterol'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:03:32
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'data entry error' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:34:04
User entered 'No (N)' reason for change: Data Entry Error		23 Oct 2020 18:34:00
User opened query 'Per DM CLR: Prophylaxis = Yes however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		10 Sep 2020 12:13:06
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'COPD'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query ""Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:40:14
' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 18:23:23
Query ""Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.		
' answered with 'updated' (Site from DM).		
User entered '180' reason for change: Data Entry Error		05 Mar 2021 18:23:09
User opened query ""Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.		09 Sep 2020 09:20:59
' (Site from DM).		
User entered '2'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:23:09
User entered 'puff (PUFF)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'twice daily (BID)'	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:05
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:03:39
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' answered with 'data entry error' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:32:31
User entered 'No (N)' reason for change: Data Entry Error		23 Oct 2020 18:32:15
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' ' (Site from DM).		09 Sep 2020 09:21:58
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:21:05

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: RANOLAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 07:39:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:39:28
Data point term sent to Coder	System	18 Aug 2020 19:21:57
User entered 'Ranolazine'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'History of CABG'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '1000'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:46
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:21:46
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM). Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'data entry error' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Nov 2020 09:03:51
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) amy sheets (b) (4) (b) (4)	23 Oct 2020 18:36:09 23 Oct 2020 18:36:04 09 Sep 2020 09:41:28

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:21:46

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:45:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 22:17:20 23 Oct 2020 22:17:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:27:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:27:05
Data point term sent to Coder User entered 'Amlodipine'	System amy sheets (b) (4)	18 Aug 2020 19:23:00 18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:04:50
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'med prescribed in association with cabg' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 22:17:20
User entered 'HISTORY OF CABG' reason for change: New Information		23 Oct 2020 22:17:16
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		09 Sep 2020 09:44:12
User entered 'Hypertension'		
	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '10'	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:22:21
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 09:43:56
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:42:58
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query '	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:05:01

Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify."

' (Site from DM).

Query '

(b) (4), (b) (6)

23 Oct 2020 18:36:23

Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify."

' answered with 'data entry error' (Site from DM).

User entered 'No (N)' reason for change: Data Entry Error

(b) (4), (b) (6)

23 Oct 2020 18:36:18

User opened query '

09 Sep 2020 09:44:35

Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify."

' (Site from DM).

User entered 'Yes (Y)'

amy sheets (b) (4)
(b) (4)

18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:22:21

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Oct 2020 13:08:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 13:08:23
Data point term sent to Coder	System	23 Oct 2020 22:19:23
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 22:18:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:36:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:36:19
Data point term sent to Coder	System	18 Aug 2020 19:24:02
User entered 'Ezetimibe'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:23:25
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:06:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'med prescribed in association with cabg' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 22:18:37
User entered 'HISTORY OF CABG' reason for change: New Information		23 Oct 2020 22:18:34
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		09 Sep 2020 10:19:16
User entered 'None'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered '10'	amy sheets (b) (4)	18 Aug 2020 19:23:25
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'mg (mg)'	amy sheets (b) (4)	18 Aug 2020 19:23:25
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:23:25
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.'" (Site from DM). Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.'" answered with 'data entry error' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:06:27
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.'" (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:36:42
	(b) (4), (b) (6)	23 Oct 2020 18:36:36
		09 Sep 2020 10:18:52
	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:23:25

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:17:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:17:26
Data point term sent to Coder	System	26 Oct 2020 12:21:15
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 12:21:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:27:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:27:08
Data point term sent to Coder	System	18 Aug 2020 19:24:10
User entered 'Flonase'	amy sheets (b) (4)	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:01:06
User closed query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:00:57
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'resolved' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:21:24
Query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'resolved' (Site from DM).		26 Oct 2020 12:21:19
User entered 'SINUSITIS' reason for change: New Information		26 Oct 2020 12:21:08
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		09 Sep 2020 06:56:41
User opened query 'Per DM CLR: Please specify the type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).		09 Sep 2020 06:55:05
User entered 'Allergies'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered '2'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Other (OTHER)'	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Spray'	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Nasal (NASAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'I'	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:09
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query '	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:00:52
Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify." ' (Site from DM). Query '	(b) (4), (b) (6)	23 Oct 2020 18:36:55
Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify." ' answered with 'data entry error' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error User opened query '		23 Oct 2020 18:36:50
Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify." ' (Site from DM). User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	09 Sep 2020 06:57:02 18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:24:09

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Oct 2020 21:10:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:10:26
Data point term sent to Coder	System	26 Oct 2020 12:29:23
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 12:29:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:27:10
Data point term sent to Coder	System	18 Aug 2020 19:25:11
User entered 'Fish Oil'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 08:34:32
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' answered with 'Subject informed me that he was not directed to take fish oil, that is is not being used to treat or prevent any specific condition - that he just takes it because "it is good for you". ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:29:20
User entered 'maintenance' reason for change: Per Query Resolution		26 Oct 2020 12:29:16
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 with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).		09 Sep 2020 09:11:31
User entered 'Cholesterol'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 08:34:31
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' ' answered with 'the pills are 1000mgs and subject takes 2 pills 2x/day ' (Site from DM).		26 Oct 2020 12:26:30
User entered '2000' reason for change: Per Query Resolution		26 Oct 2020 12:26:18
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' ' (Site from DM).		09 Sep 2020 09:12:52
User entered '2'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:26:18
User entered 'tablet (TABLET)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:45
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:26:18
User entered 'once daily (QD)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
	(b) (4)	
User entered empty.	amy sheets (b) (4)	18 Aug 2020 19:24:45
	(b) (4)	

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:20:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:29:29
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 12:26:18
User entered '1'	System	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:24:45

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 15:32:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 15:32:56
Data point term sent to Coder	System	12 Apr 2021 15:26:46
User entered 'SPIRIVA'	(b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '2.5'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'MCG'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 15:25:54

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 07:49:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:49:41
Data point term sent to Coder	System	12 Apr 2021 15:27:46
User entered 'IPRATROPIUM BROMIDE/ALBUTEROL MIX'	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '3'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:27:10

US3052044

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:55:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:59:06
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 19:24:57

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'USA-US117-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:58:07
Un-reviewed for Safety.	System	20 Apr 2021 16:09:26
Signature has been broken.	System	20 Apr 2021 16:09:26
User entered 'Yes (Y)'	System	20 Apr 2021 16:09:26
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yaa'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Oppong'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '1565 Purdue Drive'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Fayetteville'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'NC'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '28314'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'US'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:58:21
User entered '1'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'USA-US117-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:58:07
Un-reviewed for Safety.	System	20 Apr 2021 16:09:26
Signature has been broken.	System	20 Apr 2021 16:09:26
User entered 'Yes (Y)'	System	20 Apr 2021 16:09:26
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yaa'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Oppong'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '1565 Purdue Drive'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Fayetteville'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'NC'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '28314'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'US'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:58:21
User entered '1'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
User entered '13/Apr/2021 13:45'	(b) (4) System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:29

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.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'I'		13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered		
'USA-US117-2021-MRNA-1273-P301000008'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:58:07
Un-reviewed for Safety.	System	20 Apr 2021 16:09:26
Signature has been broken.	System	20 Apr 2021 16:09:26
User entered 'Yes (Y)'	System	20 Apr 2021 16:09:26
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yes (Y)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'No (N)'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Yaa'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Oppong'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '1565 Purdue Drive'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'Fayetteville'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'NC'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered '28314'	System	13 Apr 2021 17:44:58

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'US'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:58:21
User entered '1'	System	13 Apr 2021 17:45:12

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
User entered '21/Apr/2021 09:58'	(b) (4) System	21 Apr 2021 14:58:21

US3052044

Folder: SAE USA-US117-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:19:15
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:46:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:58:21