US3052028 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:01:43

All time stamps listed in this document are displayed in GMT

US3052028

Form: Participant Creation

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Participant ID	US3052028

mRNA-1273-P301 Completion Guidelines

US3052028

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3052028

Folder: Screening

Form: Demographics

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female ●
	Male ○
Ethnicity	Hispanic or Latino ○
	Not Hispanic or Latino ●
	Not Reported ○
	Unknown ○

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **23 Feb 2021 07:49:22**

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Date of Informed Consent *(dd MMM yyyy)*	30 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

US3052028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Did the participant meet all eligibility criteria?　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Were any significant conditions reported?　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	SINUS FISTULA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3052028

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	ASTHMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3052028

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3052028

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Apr 2021 13:24:24

Generated On: 09 Jun 2021 15:01:43

Condition	HEARTBURN
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ◯
	No ⬤
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)	

US3052028

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ◯
	No ⬤
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)	

US3052028

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	BENIGN COLON MASS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	MILD INCONTENENCE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	TRANSIENT ISCHEMIC ATTACK
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	TRANSIENT ISCHEMIC ATTACK
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	ANXIETY/DEPRESSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	PTSD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
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) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	ALLERGY TO ANTI REFLUX MEDICATIONS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	ALLERGY TO ERYTHOMYACIN
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	DIABETES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 01 Apr 2021 13:24:24

Generated On: 09 Jun 2021 15:01:43

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	DILATATION AND CURETTAGE
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	ABDOMINAL LAPAROSCOPY
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	UTERINE SUSPENSION SURGERY
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	NOSE & SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	HERPES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Condition	MUSCLE SPASMS IN BACK
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	16:30 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 16:30
Height *(xxx.x)*	64.5 in
Weight *(xxx.x)*	150 lb
BMI *(xxx.x)*	25.40281 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?   Yes ●

                                                                            No ○

Date of examination *(dd MMM yyyy)*   30 JUL 2020

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

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **23 Feb 2021 07:49:22**

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Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Is the participant of childbearing potential?	Yes ◯
	No ⬤
If No, what is the reason?	Surgically sterile ◯
	Post-menopausal ⬤
	Partner medically sterile ◯
	Not reached age of Menarche ◯
	Other ◯
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	True

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Folder: Screening

Form: Risk of Exposure

Data signed: [(b) (4)] 23 Feb 2021 07:49:22

Generated On: 09 Jun 2021 15:01:43

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	NOT CURRENTLY EMPLOYED

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 07:49:22**

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

What was the date of randomization? *(dd MMM yyyy)*	30 JUL 2020
What was the participant's randomization number?	142416

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 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	16:31 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 16:31
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	30 JUL 2020
Time of assessment *(00:00-23:59)*	18:30 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 18:30
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 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 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?

Yes ⭕

No ⚫

Date of examination *(dd MMM yyyy)* _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

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)*	30 JUL 2020
What was the treatment time? *(00:00-23:59)*	18:01 (24 HR)
Treatment Date and Time (derived)	30 JUL 2020 18:01
Which arm was used to give treatment?	Left Arm ○
	Right Arm ●
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3052028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	30 JUL 2020
Collection time *(00:00-23:59)*	17:54 (24 HR)
Collection date and time (derived)	30 JUL 2020 17:54

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*			30 JUL 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:57	30 JUL 2020 17:57
Nasopharyngeal Swab 2	No		

US3052028
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

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**	98.2 °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	30 JUL 2020 18:49
PC Open Date & Time	30 JUL 2020 18:21
PC Close Date & Time	30 JUL 2020 20:51

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**	98.6 °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	30 JUL 2020 23:27
PC Open Date & Time	30 JUL 2020 21:46
PC Close Date & Time	31 JUL 2020 11:59

FDA-CBER-2022-1614-0215382

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43

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	01 AUG 2020 00:20
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	01 AUG 2020 22:30
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43

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	02 AUG 2020 22:21
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

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**	97.9 °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	03 AUG 2020 23:03
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43

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**	96.5 °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	04 AUG 2020 23:10
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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	30 JUL 2020 18:50
PC Open Date & Time	30 JUL 2020 18:21
PC Close Date & Time	30 JUL 2020 20:51

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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	30 JUL 2020 23:28
PC Open Date & Time	30 JUL 2020 21:46
PC Close Date & Time	31 JUL 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 2

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**	1
Measure the largest size across any injection site swelling/hardness with the ruler provided.	

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ◯
	Does not interfere with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	01 AUG 2020 00:24
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	01 AUG 2020 22:31
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	02 AUG 2020 22:22
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	03 AUG 2020 23:04
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 6

Please record - PAIN AT INJECTION SITE.
Please select one response below

- None ⬤
- Does not interfere with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

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

- Yes ◯
- No ⬤

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

- Yes ◯
- No ⬤

Please record - UNDERARM GLAND SWELLING OR TENDERNESS.
Please select one response below

- None ◯
- Does not interfere with activity ⬤
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	04 AUG 2020 23:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 7

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 ◯

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

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

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

- Yes ◯
- No ◯

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
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	_____
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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	○

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	30 JUL 2020 18:51
PC Open Date & Time	30 JUL 2020 18:21
PC Close Date & Time	30 JUL 2020 20:51

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

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 ○

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	30 JUL 2020 23:29
PC Open Date & Time	30 JUL 2020 21:46
PC Close Date & Time	31 JUL 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43

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 ⬤

	Yes ◯
PC Time stamp	01 AUG 2020 00:26
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43

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 ●

	Yes 〇
PC Time stamp	01 AUG 2020 22:32
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

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

FDA-CBER-2022-1614-0215405

	Yes ◯
PC Time stamp	02 AUG 2020 22:22
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

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 ●

	Yes
PC Time stamp	03 AUG 2020 23:04
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43

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 ●

Yes ◯

PC Time stamp	04 AUG 2020 23:12
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

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 ◯

	Yes ◯
PC Time stamp	
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052028
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ○ Yes ●
PC Time stamp	06 AUG 2020 22:30
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

TIMEPOINT	DAY 8
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	06 AUG 2020 22:31
PC Open Date and Time	06 AUG 2020 12:00
PC Close Date and Time	07 AUG 2020 11:59

US3052028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 08 AUG 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

US3052028

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3052028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 17 AUG 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3052028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

| 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

US3052028

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

                                                                            No ◯

Continuing Flag   1

Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **23 Feb 2021 07:49:23**
Generated On: 09 Jun 2021 15:01:43

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | VISIT2 |

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	15:18 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:18
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	16:56 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 16:56
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

US3052028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4)   **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?   Yes ●

                                                            No ○

Date of examination *(dd MMM yyyy)*   25 AUG 2020

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

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)*	25 AUG 2020
What was the treatment time? *(00:00-23:59)*	16:26 (24 HR)
Treatment Date and Time (derived)	25 AUG 2020 16:26

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

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	25 AUG 2020
Collection time *(00:00-23:59)*	15:36 (24 HR)
Collection date and time (derived)	25 AUG 2020 15:36

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*			25 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:48	25 AUG 2020 15:48
Nasopharyngeal Swab 2	No		

US3052028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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**	98.0 °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	25 AUG 2020 16:57
PC Open Date & Time	25 AUG 2020 16:46
PC Close Date & Time	25 AUG 2020 19:16

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| Was **TEMPERATURE** taken? | Yes ⬭ |
| | No ⬭ |

Please record your **TEMPERATURE in °F**	

| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ⬭ |
| | No ⬭ |

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	25 AUG 2020 20:11
PC Close Date & Time	26 AUG 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

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**	99.2 °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 22:29
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:43

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43

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**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯

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

To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43

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**	94.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

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

PC Time Stamp	30 AUG 2020 22:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

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**	93.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	31 AUG 2020 22:01
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43

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 ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** 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	
PC Open Date & Time	25 AUG 2020 16:46
PC Close Date & Time	25 AUG 2020 19:16

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** 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	
PC Open Date & Time	25 AUG 2020 20:11
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0215438

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 2
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 22:29
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

TIMEPOINT	DAY 3

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 ◯

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

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

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

- Yes ◯
- No ◯

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
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	_____
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 4

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 ◯ |

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

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

| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ◯ |
| | No ◯ |

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** 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	_____
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 5
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 ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** 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	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-0215442

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 6

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	30 AUG 2020 22:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 7
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 AUG 2020 22:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-0215444

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43

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	◯

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯

PC Time stamp	
PC Open Date & Time	25 AUG 2020 16:46
PC Close Date & Time	25 AUG 2020 19:16

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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 ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯
	Yes ◯

PC Time stamp	
PC Open Date & Time	25 AUG 2020 20:11
PC Close Date & Time	26 AUG 2020 11:59

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 ⬤

	Yes ◯
PC Time stamp	27 AUG 2020 01:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

TIMEPOINT	DAY 3

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

FATIGUE	
None	◯
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY	
None	◯
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS	
None	◯
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

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

CHILLS	
None	◯
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ◯

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Yes ◯

PC Time stamp	
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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 ◯

Yes ◯

PC Time stamp	
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43

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 ⬭

	Yes ◯
PC Time stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

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 ⬤

	Yes ◯
PC Time stamp	30 AUG 2020 22:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43

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 ●

	Yes ○
PC Time stamp	31 AUG 2020 22:03
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ●
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
PC Time Stamp	01 SEP 2020 22:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052028

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	01 SEP 2020 22:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052028
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3052028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

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 _____

US3052028

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

                                                                                                                      No ○

Continuing Flag   1

US3052028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 16 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3052028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 07:49:23**

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	10:20 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:20
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0215470

US3052028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

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.

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	10:45 (24 HR)
Collection date and time (derived)	29 SEP 2020 10:45

US3052028
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?　　　　　Yes ●

No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　1

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2020 00:01
Patient Cloud Close Date & Time	03 OCT 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ◯

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

Symptom	
Fever (Temperature ≥ 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 ○

FDA-CBER-2022-1614-0215478

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯
  - Yes ◯

Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-0215482

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

FDA-CBER-2022-1614-0215484

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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):

Symptom	
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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

FDA-CBER-2022-1614-0215490

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ◯

FDA-CBER-2022-1614-0215492

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

Symptom	
Fever (Temperature ≥ 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 ○

FDA-CBER-2022-1614-0215494

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 166**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0215502

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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):

Symptom	
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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ○
Have 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):	
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 ●
Please contact your study clinic immediately. Click below to confirm that you have read this 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	30 JAN 2021 00:52:08
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

Symptom	
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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 201**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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	21 FEB 2021 03:27:50
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⚪
Have 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):	
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 ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this 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	27 FEB 2021 00:02:37
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⚪
Have 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):	
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 ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this 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	09 MAR 2021 03:41:57
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
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 ⬤
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 ⬤

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 MAR 2021 00:05:13
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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	20 MAR 2021 04:46:55
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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	27 MAR 2021 00:25:42
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯
Have 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):	
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 ●
Please contact your study clinic immediately. Click below to confirm that you have read this 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	03 APR 2021 00:04:52
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⬤(empty) Yes ⬤(filled)
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤(filled) Yes ⬤(empty)
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤(filled) Yes ⬤(empty)
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤(empty) Yes ⬤(filled)
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤(filled)
Date and time of submission	12 APR 2021 15:05:01
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⚪
Have 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):	
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 ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this 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	19 APR 2021 12:54:01
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Symptom	
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 ⭕

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 278**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0215527

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

FDA-CBER-2022-1614-0215529

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-0215531

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ○

FDA-CBER-2022-1614-0215533

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ⃝

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 327

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0215539

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⚪
Yes ⚪

Have you been exposed to someone with known SARS-CoV-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 ⚪

FDA-CBER-2022-1614-0215541

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯
Yes ◯

Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-0215543

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 355**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⟨⟩ Yes ⟨⟩
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⟨⟩ Yes ⟨⟩
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⟨⟩
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⟨⟩ Yes ⟨⟩

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

Symptom	
Fever (Temperature ≥ 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 ⟨⟩

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ⭘

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

FDA-CBER-2022-1614-0215551

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 JUL 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⭕

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 AUG 2021 00:01
Patient Cloud Close Date & Time	11 AUG 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 390**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0215557

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⭕

FDA-CBER-2022-1614-0215559

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	28 AUG 2021 00:01
Patient Cloud Close Date & Time	01 SEP 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-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 ⃝

FDA-CBER-2022-1614-0215563

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯ |
| | Yes ◯ |

| Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯ |

FDA-CBER-2022-1614-0215567

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0215569

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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

FDA-CBER-2022-1614-0215571

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 453**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪
	Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪
	Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪
	Yes ⚪

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

Fever (Temperature ≥ 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 ⚪

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⭘

FDA-CBER-2022-1614-0215581

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-0215585

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0215587

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ⭘

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⃝

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 544**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately	⭘
Date and time of submission		
Patient Cloud Open Date & Time	29 JAN 2022 00:01	
Patient Cloud Close Date & Time	02 FEB 2022 23:59	

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⃝

FDA-CBER-2022-1614-0215605

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ⃝

FDA-CBER-2022-1614-0215607

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⭕

FDA-CBER-2022-1614-0215611

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ⃝

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 MAR 2022 00:01
Patient Cloud Close Date & Time	09 MAR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ⃝
Yes ⃝

Have you been exposed to someone with known SARS-CoV-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 ⃝

FDA-CBER-2022-1614-0215617

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	23 MAR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT　　　　　　　　　　　　　　　　　　　DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0215619

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately	◯
Date and time of submission		
Patient Cloud Open Date & Time	09 APR 2022 00:01	
Patient Cloud Close Date & Time	13 APR 2022 23:59	

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

FDA-CBER-2022-1614-0215627

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-0215629

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 MAY 2022 00:01
Patient Cloud Close Date & Time	11 MAY 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0215633

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2022 00:01
Patient Cloud Close Date & Time	18 MAY 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°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 ⭕

FDA-CBER-2022-1614-0215637

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2022 00:01
Patient Cloud Close Date & Time	01 JUN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

FDA-CBER-2022-1614-0215639

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 684**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

TIMEPOINT DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⟨ ⟩
Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

FDA-CBER-2022-1614-0215649

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ⚪

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	**DAY 726**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2022 00:01
Patient Cloud Close Date & Time	10 AUG 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 ≥ 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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

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°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 ◯

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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):

Symptom	
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 ○

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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°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 ◯

FDA-CBER-2022-1614-0215669

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT	DAY 789

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

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

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

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

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

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

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

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

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT   **DAY 796**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3052028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:01:43

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		09 MAR 2021 03:42:15

US3052028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3052028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 NOV 2020 |

| Please select one status for the follow-up contact | Contact Made ○ |
| | Contact Not Made ● |

| Comments | LEFT VOICEMAIL |

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

          No ○

Continuing Flag   1

US3052028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 DEC 2020

Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3052028
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 FEB 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	VM FULL

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3052028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	02 MAR 2021
Time of assessment *(00:00-23:59)*	14:50 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 14:50
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Mar 2021 14:47:09**
Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 2 MAR 2021

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

US3052028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	2 MAR 2021
Collection time *(00:00-23:59)*	15:19 (24 HR)
Collection date and time (derived)	2 MAR 2021 15:19

US3052028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

                                                                No ◯

Continuing Flag   1

US3052028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 20:19:23**

Generated On: 09 Jun 2021 15:01:43

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*	SUBJECT REPORTED UNDERGOING A CHOLECYSTECTOMY DUE TO CHOLECYSTITIS THAT OCCURRED 10MAR2021

US3052028

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 13:24:24**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ●

                                                                                                                      No ◯

Continuing Flag   1

US3052028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 12:26:17**

Generated On: 09 Jun 2021 15:01:43

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 APR 2021 |

| Please select one status for the follow-up contact | Contact Made ○ |
| | Contact Not Made ● |

| Comments | LEFT VOICEMAIL |

If Contact Not Made, please provide Comments

US3052028

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 12:26:17**

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?   Yes ⬤

                                                                No ◯

Continuing Flag   1

US3052028

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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 _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3052028
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Date of Contact

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ◯

Clinical Visit - Unscheduled ◯

Safety Call ◯

Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ◯

No ◯

US3052028
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **23 Feb 2021 07:49:22**
Generated On: 09 Jun 2021 15:01:43

Generate Next COVID-19 Assessment

Yes ○
No ○

US3052028

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

Form: Visit Date

Data signed: (b) (4) **15 Mar 2021 14:47:09**

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	23 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	20 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	12 JAN 2021
Participant randomization assignment	mRNA-1273 ●
	Placebo ○
Actual Dose 1	mRNA-1273 ●
	Placebo ○
	Not Administered ○
Actual Dose 2	mRNA-1273 ●
	Placebo ○
	Not Administered ○
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	
Continuing with mRNA-1273	

US3052028

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **25 Feb 2021 21:21:27**

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	20 FEB 2021
Collection time *(00:00-23:59)*	15:32 (24 HR)
Collection date and time (derived)	20 FEB 2021 15:32

US3052028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **25 Feb 2021 21:21:27**

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	20 FEB 2021
Collection time *(00:00 - 23:59)*	15:34
Collection Date and Time (derived)	20 FEB 2021 15:34

US3052028

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **23 Feb 2021 07:49:22**

Generated On: 09 Jun 2021 15:01:43

Did the participant experience any adverse events?   Yes ●

                                                            No ◯

If Yes, enter details on the Adverse Events form.

US3052028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

AEID	USA-US117-2020-MRNA-1273-P30 1000001
Adverse event	CHEST PAIN NOS

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)*	05 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	06 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	05 AUG 2020
Hospital Discharge Date *(dd MMM yyyy)*	06 AUG 2020

Admitted to ICU? Yes ○ No ● Unknown ○

Folder: Adverse Events
Form: Adverse Events (1)
Data signed: ▨ (b) (4) ▨ **03 May 2021 17:06:43**
Generated On: 09 Jun 2021 15:01:43

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 ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	None ⬤
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

	PATIENT WAS PRESENTED WITH STABBING CHEST PAIN THAT RADIATES LATERALLY FROM HER STERNUM. THE PAIN LASTED 30 MINUTES UNTIL SHE WAS GIVEN NITROGLYCERIN BY EMS. THE NITROGLYCERIN STOPPED HER PAIN. NOTHING MADE THE PAIN WORSE, NO SHORTNESS OF BREATH.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3052028

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

AEID	
Adverse event	ABDOMINAL PAIN FOLLOWING SURGERY

Was this a medically-attended AE?   Yes ○   No ●

Was this a Solicited Adverse Reaction?   Yes ○   No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○   No ●

Start date *(dd MMM yyyy)*	11 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○   No ●

If not Ongoing, end date *(dd MMM yyyy)*	12 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ●   Grade 2/Moderate ○   Grade 3/Severe ○   Grade 4 ○

Is the adverse event serious?   Yes ○   No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?   Yes ○   No ○   Unknown ○

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Folder: Adverse Events

Form: Adverse Events (4)

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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 ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **03 May 2021 17:06:43**

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AEID	USA-US117-2021-MRNA-1273-P30 1000006
Adverse event	MUSCULOSKELETAL CHEST PAIN

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)* — 03 APR 2021

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing? Yes ○ No ●

  If not Ongoing, end date *(dd MMM yyyy)* — 04 APR 2021

  End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	03 APR 2021
Hospital Discharge Date *(dd MMM yyyy)*	04 APR 2021

  Admitted to ICU? Yes ○ No ● Unknown ○

US3052028

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 17:06:43

Generated On: 09 Jun 2021 15:01:43

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	●
	Related	○
	Not Applicable	○
Relationship to Study Procedure	Not Related	●
	Related	○
	Not Applicable	○
Action taken with investigational product	None	○
	Dose Delayed	○
	Investigational Product Withdrawn	○
	Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	○
	Not Recovered/Not Resolved	○
	Recovered/Resolved	●
	Recovered/Resolved with Sequelae	○
	Recovering/Resolving	○
	Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ADMITTED TO THE HOSPITAL PER THE PATIENT SHE WAS GIVEN IV FLUIDS, ANTIBIOTICS, AND BREATHING TX. HER RECORDS HAVE BEEN REQUESTED.
Serious Adverse Event Derived (CSA Programming Field Ony)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **03 May 2021 17:06:43**

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Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **15 Mar 2021 14:47:09**

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

                                                                          No ◯

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

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	GLIPIZIDE

Prophylaxis

Yes ◯
No ⬤

Indication	DIABETES MILITUS
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 ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	PIOGLIPIZIDE

Prophylaxis

Yes ◯

No ⬤

Indication	DIABETES MILLITUS
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 ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ⚪
	No ⚫
Indication	HYPOTHROIDISM
Dose per administration	50
Dose unit	mg ⚪
	ug ⚫
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚫
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2013
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	L-LYSINE

Prophylaxis	Yes ⚪
	No ⬤

Indication	HERPES

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)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	True
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	FLONASE
Prophylaxis	Yes ⚪
	No ⚫
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg ⚪
	ug ⚫
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚫
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	⬤
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	5 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **03 May 2021 17:06:43**

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Name of Medication	GLIMEPIRIDE
Prophylaxis	Yes ○
	No ●
Indication	DIABETES
Dose per administration	4
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	True
Ongoing?	Yes ●
	No ○
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ●

Name of Medication	METHOCARBAMOL

Prophylaxis	Yes ◯
	No ⬤

Indication	MUSCLE SPASMS

Dose per administration	1500

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)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	True
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	PIAGLITAZON

Prophylaxis	Yes ⚪
	No ⚫

Indication	DIABETES

Dose per administration	15

Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚫
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪

If frequency is Other, specify	

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	NITROGLYCERIN

Prophylaxis	Yes ◯
	No ⬤

Indication	CHEST PAIN NOS
Dose per administration	2.5

Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ⬤
	unknown ◯
	other ◯

If frequency is Other, specify _____

Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	5 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	5 AUG 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **03 May 2021 17:06:43**
Generated On: 09 Jun 2021 15:01:43

Name of Medication	ALBUTEROL

Prophylaxis

Yes ◯
No ⬤

Indication	SHORTNESS OF BREATH/WHEEZING
Dose per administration	20

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	◯
Intramuscular	◯
Respiratory (Inhalation)	⬤
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	06 APR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **03 May 2021 17:06:43**

Generated On: 09 Jun 2021 15:01:43

Name of Medication	CEFPODOXIME

Prophylaxis	
Yes	⚪
No	⬤

Indication	KIDNEY INFECTION
Dose per administration	200

Dose unit	
mg	⬤
ug	⚪
mL	⚪
g	⚪
IU	⚪
tablet	⚪
capsule	⚪
puff	⚪
Other	⚪

If dose unit is Other, specify	

Frequency	
once daily	⚪
twice daily	⬤
three times daily	⚪
four times daily	⚪
every other day	⚪
every week	⚪
every month	⚪
as needed	⚪
once	⚪
unknown	⚪
other	⚪

If frequency is Other, specify	

Route of administration	
Oral	⬤
Topical	⚪
Subcutaneous	⚪
Transdermal	⚪
Intraocular	⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	06 APR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **07 Apr 2021 15:18:53**

Generated On: 09 Jun 2021 15:01:43

Were any concomitant procedures performed?

Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **07 Apr 2021 15:18:53**

Generated On: 09 Jun 2021 15:01:43

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	CHOLECYSTECTOMY	Medical History	

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

US3052028
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) 23 Feb 2021 07:49:22
Generated On: 09 Jun 2021 15:01:43

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

Reason for discontinuation	
AE (specify)	◯
SAE (specify)	◯
Complete	◯
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Other	◯

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

If reason for discontinuation is Death, main cause of death	
Adverse event	◯
Unknown	◯
Other	◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?	
Yes	◯
No	◯
Unknown	◯

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	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)	8

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	06/AUG/2020 11:04
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	08/OCT/2020 11:19
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	11/NOV/2020 16:35
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	12/NOV/2020 07:44
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form (6)
Data signed: (b) (4) **07 Apr 2021 15:18:54**
Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	01/DEC/2020 16:07
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	22/DEC/2020 16:29
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.	True

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	24/MAR/2021 15:01
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

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: ▓▓ (b) (4) ▓▓ **07 Apr 2021 15:18:54**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2020-MRNA-1273-P30 1000001
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	

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.

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Data signed: (b) (4) **03 May 2021 12:21:12**
Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	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)	6

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form (1)
Data signed: (b) (4) **03 May 2021 12:21:12**
Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	05/APR/2021 06:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form (2)
Data signed: (b) (4) **03 May 2021 12:21:12**
Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 08:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) **03 May 2021 12:21:12**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	15/APR/2021 10:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) **03 May 2021 12:21:12**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	16/APR/2021 09:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) **03 May 2021 12:21:12**

Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ⬤ No ⭘
Death	Yes ⭘ No ⬤
Life threatening	Yes ⭘ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ⭘
Persistent or significant disability or incapacity	Yes ⭘ No ⬤
Congenital anomaly or birth defect	Yes ⭘ No ⬤
Other medically important event	Yes ⭘ No ⬤
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	28/APR/2021 09:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form (6)
Data signed: (b) (4) **03 May 2021 12:21:12**
Generated On: 09 Jun 2021 15:01:43

SAEID	USA-US117-2021-MRNA-1273-P30 1000006
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	03/MAY/2021 07:58
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

US3052028 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052028

Form: Participant Creation

Generated On: 09 Jun 2021 15:01:43

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'US3052028'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:04:19

US3052028
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:22:49

US3052028
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:04:19

US3052028
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Clinic (Clinic)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:22:49

US3052028
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'SCRN'	System	30 Jul 2020 22:22:49

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:04:20

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 08:55:36
Query 'Per CDM: Please complete this form.' answered with 'Reviewed and completed' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:09
User entered '60'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 11:21:50

US3052028
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:01:43
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'YEARS'	System	02 Sep 2020 18:40:42

US3052028
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:01:43

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '60'	System	30 Jul 2020 22:23:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Female (F)'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

FDA-CBER-2022-1614-0215764

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:01:43
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '1'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:40:42
	(b) (4)	

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:01:43
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:01:43
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Nicole Davis (b) (4) (b) (4)	02 Sep 2020 18:40:42

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered '30 Jul 2020'	amy sheets (b) (4)	30 Jul 2020 22:23:05
	(b) (4)	

US3052028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:43

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jul 2020'	System	30 Jul 2020 22:23:05

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2020'	System	30 Jul 2020 22:23:05

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Amendment 1 (1)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:23:05

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 22:23:05
	(b) (4)	

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:23:05

Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:23:05

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered 'No (N)'	amy sheets (b) (4)	30 Jul 2020 22:23:05
	(b) (4)	

US3052028
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:01:43
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:04:19

US3052028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:43

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1'	System	30 Jul 2020 22:23:13

US3052028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:01:43

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:23:13

US3052028

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:01:43

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:27:43

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:31:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:31:43
Data point term sent to Coder	System	02 Oct 2020 13:30:09
User entered 'cataracts'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 18:11:20
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 18:11:27
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:16

US3052028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:16

US3052028
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:16

US3052028
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Soft tissue disorders NEC, PT: Fistula, LLT: Fistula - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:08:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:08:45
Data point term sent to Coder	System	02 Oct 2020 13:30:09
User entered 'sinus fistula'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of NOSE & SINUS SURGERY was performed in UNK 1992. Please review and update if appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:07:16
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of NOSE & SINUS SURGERY was performed in UNK 1992. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:53:45
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:32

US3052028
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:01:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:32

US3052028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:32

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:32

US3052028
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:32

US3052028
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:11:48
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:54:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:31:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:31:43
Data point term sent to Coder	System	02 Oct 2020 13:30:09
User entered 'asthma'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:29:46

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:30:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:45:40
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:30:23
Data point term sent to Coder	System	11 Nov 2020 20:30:21
Coding entries removed.	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:30:18
User entered 'Hyperlipidemia' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:30:18
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:54:48
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: High density lipoprotein, LLT: HDL - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:33:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:33:22
Data point term sent to Coder	System	02 Oct 2020 13:32:16
User entered 'hdl'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

FDA-CBER-2022-1614-0215818

US3052028
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:03

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:03

US3052028
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:03

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:03

US3052028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:03

US3052028
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:33:51
Data point term sent to Coder	System	02 Oct 2020 13:33:19
User entered 'heartburn'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	09 Oct 2020 12:28:59
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	02 Oct 2020 13:32:19
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '1' reason for change: Data Entry Error	(b) (4) Avia McClain-Stocker (b) (4)	09 Oct 2020 12:28:59
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	09 Oct 2020 12:29:16
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:29:16
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	09 Oct 2020 12:28:59
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '1' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:28:59
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:32:19

US3052028
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:01:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:19

US3052028
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:19

US3052028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:32:19

US3052028
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:34:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:34:53
Data point term sent to Coder	System	02 Oct 2020 13:34:20
User entered 'hiatal hernia'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

US3052028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

US3052028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

US3052028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:20

US3052028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:20

US3052028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:20

US3052028
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:20

US3052028
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
User closed query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:14:37
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms benign, HLT: Gastrointestinal neoplasms benign NEC, PT: Large intestine benign neoplasm, LLT: Benign colonic neoplasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:49:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:49:48
Query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:32:57
Data point term sent to Coder	System	29 Mar 2021 16:32:41
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 16:32:10
Signature has been broken.		29 Mar 2021 16:32:10
User entered 'benign colon mass' reason for change: Data Entry Error		29 Mar 2021 16:32:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Intestinal mass, LLT: Large intestine mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:32:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:32:49

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 02:43:39
User closed query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:43:16
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Data point term sent to Coder	System	25 Feb 2021 13:48:27
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 13:48:24
User entered 'MASS TO COLON' reason for change: Data Entry Error		25 Feb 2021 13:48:24
Query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'colonoscopy has not yet occurred' (Site from DM).		25 Feb 2021 13:48:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Intestinal mass, LLT: Large intestine mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:57:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:57:11
User opened query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:55:06

PRODUCTION RELEASE (v12.003 EAB) (1725)

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Oct 2020 13:34:20
User entered 'mass to colon-pending colonoscopy'	Stacey Saldua (b) (4)	02 Oct 2020 13:33:58
	(b) (4)	

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:58

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:58

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:58

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:58

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:33:58

US3052028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:58

US3052028
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:58

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:58

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:33:58

FDA-CBER-2022-1614-0215858

US3052028
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please review and update the MH Condition to include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:12:30
User opened query 'Per DM CLR: Please review and update the MH Condition to include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:18:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Incontinence, LLT: Incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:29:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:29:40
Data point term sent to Coder	System	02 Oct 2020 13:35:21
User entered 'mild incontenence'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:34:37

US3052028
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:34:37

US3052028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:34:37

US3052028
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:53:55
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:29:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:29:36
Data point term sent to Coder	System	11 Nov 2020 20:28:17
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:49
Coding entries removed.	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:36
User entered 'Transient Ischemic attack' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:36
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:55:50
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:37:49

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Oct 2020 13:36:22
User entered 'TIA'	Stacey Saldua (b) (4)	02 Oct 2020 13:35:28
	(b) (4)	

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 2013'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'un UNK 2013' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:36
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:35:28

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Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:54:16
Query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'updated per source' (Site from DM).	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:56
User entered '0' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:27:36
User opened query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:56:11
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:35:28

US3052028
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:01:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 2013'	System	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2013'	System	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 2013'	System	11 Nov 2020 20:27:36
User entered empty.	System	02 Oct 2020 13:35:28

US3052028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2013'	System	11 Nov 2020 20:27:36
User entered empty.	System	02 Oct 2020 13:35:28

US3052028
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:54:31
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:29:38
Data point term sent to Coder	System	11 Nov 2020 20:28:17
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:14
Coding entries removed.	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:10
User entered 'Transient Ischemic attack' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:10
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Transient Ischemic attack" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:56:58
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:37:49

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US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Oct 2020 13:36:23
User entered 'tia'	Stacey Saldua (b) (4)	02 Oct 2020 13:36:00
	(b) (4)	

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 2017'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'un UNK 2017' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:10
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:54:34
Query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'reviewed source and updated accordingly' (Site from DM).	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:26
User entered '0' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 20:28:10
User opened query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this medical condition. The duration of the effects related to TIA may be unknown but the stop date of the event itself is not. Please verify the start and stop date of this medical condition as this typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:57:07
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:00

Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:01:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 2017'	System	02 Oct 2020 13:36:00

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2017'	System	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 2017'	System	11 Nov 2020 20:28:10
User entered empty.	System	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2017'	System	11 Nov 2020 20:28:10
User entered empty.	System	02 Oct 2020 13:36:00

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Anxiety depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:38:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:38:46
Data point term sent to Coder	System	02 Oct 2020 13:37:23
User entered 'anxiety/depression'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:36:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:36:42

US3052028
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:36:42

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Posttraumatic stress disorder" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary. ' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 22:10:52
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Posttraumatic stress disorder" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:57:39
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:38:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:38:45
Data point term sent to Coder	System	02 Oct 2020 13:37:24
User entered 'ptsd'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	09 Oct 2020 13:23:05
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Oct 2020 13:37:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

FDA-CBER-2022-1614-0215904

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

FDA-CBER-2022-1614-0215905

US3052028
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:01:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '0' reason for change: Data Entry Error	(b) (4) Avia McClain-Stocker (b) (4)	09 Oct 2020 13:23:05
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:37:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:37:12

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:33:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:33:37
Data point term sent to Coder	System	02 Oct 2020 13:38:24
User entered 'allergy to anti reflux medications'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:07

US3052028

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:07

US3052028
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:07

US3052028
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 14:25:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 14:25:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:10:49
Data point term sent to Coder	System	02 Oct 2020 13:39:26
User entered 'allergy to erythomyacin'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:33

US3052028

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:33

US3052028
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:01:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:33

US3052028
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:33

US3052028
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:39:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:39:50
Data point term sent to Coder	System	02 Oct 2020 13:39:26
User entered 'diabetes'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:49

US3052028
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:49

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:49

US3052028
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:38:49

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:54:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:54:28
Data point term sent to Coder	System	15 Oct 2020 19:53:55
Coding entries removed.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:53:07
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:53:07
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:39:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:39:51
Data point term sent to Coder	System	02 Oct 2020 13:39:26
User entered 'hypothyroid'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:10

US3052028

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:10

US3052028
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:10

US3052028
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a seperate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:47:55
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a seperate entry). Please verify and update as appropriate. ' answered with 'no reason given by subject' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 13:47:21
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a seperate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:04:53
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Dilatation and Curettage" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:19:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: Uterine dilation and curettage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:00:47

US3052028
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Dilatation and Curettage" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' answered with 'updated. please review' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:00:05
Data point term sent to Coder	System	22 Dec 2020 16:59:48
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 16:59:38
User entered 'Dilatation and Curettage' reason for change: Data Entry Error		22 Dec 2020 16:59:38
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please review if the term of "Dilatation and Curettage" better reflects this medical condition instead the abbreviation and reconcile with the Con Med eCRF as necessary.' (Site from DM).		22 Oct 2020 19:58:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: D & C - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:41:45
Data point term sent to Coder	System	02 Oct 2020 13:40:29
User entered 'd & c'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1984'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

US3052028
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:01:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:08:35
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:58:22
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:39:51

Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:01:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1984'	System	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1984'	System	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	02 Oct 2020 13:39:51

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Laparoscopy, LLT: Laparoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:43:46
Data point term sent to Coder	System	02 Oct 2020 13:42:31
User entered 'abdominal laparoscopy'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:01:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1991'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1991'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:42:00

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1991'	System	02 Oct 2020 13:42:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1991'	System	02 Oct 2020 13:42:00

US3052028

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1991'	System	02 Oct 2020 13:42:00

US3052028
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1991'	System	02 Oct 2020 13:42:00

US3052028
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:30:48
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:58:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysteropexy, LLT: Uterine suspension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:02:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 08:02:42
Data point term sent to Coder	System	02 Oct 2020 13:43:32
User entered 'uterine suspension surgery'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1991'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1991'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1991'	System	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1991'	System	02 Oct 2020 13:43:09

US3052028
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:01:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1991'	System	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1991'	System	02 Oct 2020 13:43:09

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:10:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:10:10
Data point term sent to Coder	System	02 Oct 2020 13:49:40
User entered 'nose & sinus surgery'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1992'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1993'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

US3052028
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:01:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1992'	System	02 Oct 2020 13:49:07

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Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1992'	System	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1993'	System	02 Oct 2020 13:49:07

US3052028

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1993'	System	02 Oct 2020 13:49:07

US3052028
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:51:54
Data point term sent to Coder	System	02 Oct 2020 13:50:40
User entered 'c-section'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1989'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:01:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1989'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:01:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1989'	System	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1989'	System	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1989'	System	02 Oct 2020 13:49:57

US3052028

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1989'	System	02 Oct 2020 13:49:57

US3052028
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:52:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 13:52:42
Data point term sent to Coder	System	02 Oct 2020 13:51:48
User entered 'c-section'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1992'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

US3052028
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

US3052028

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

US3052028

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 1992'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

US3052028
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:01:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:50:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1992'	System	02 Oct 2020 13:50:49

US3052028

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1992'	System	02 Oct 2020 13:50:49

US3052028

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 1992'	System	02 Oct 2020 13:50:49

US3052028
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '1992'	System	02 Oct 2020 13:50:49

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes virus infection, LLT: Herpes NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:11:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:11:44
Data point term sent to Coder	System	22 Dec 2020 17:11:04
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 17:10:27
User entered 'herpes' reason for change: Data Entry Error		22 Dec 2020 17:10:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Unevaluable event, LLT: Unevaluable event - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:48:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:48:17
Data point term sent to Coder	System	14 Dec 2020 20:28:36
Query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (e.g. Hyperlysinemia etc.)' canceled (Site from System).	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:28:05
User opened query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (e.g. Hyperlysinemia etc.)' (Site from System).	Coder Import (b) (4) (b) (4)	16 Nov 2020 11:49:41
Data point term sent to Coder	System	11 Nov 2020 16:46:30
User entered 'L-Lyseine' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:46:01
User entered 'Herpes'	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:01:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:43

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	11 Nov 2020 16:45:43

US3052028
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	11 Nov 2020 16:45:43

US3052028

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	11 Nov 2020 16:45:43

US3052028
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	11 Nov 2020 16:45:43

US3052028
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:01:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:55:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:55:54
Data point term sent to Coder	System	22 Dec 2020 16:54:44
User entered 'post menopausal'	(b) (4), (b) (6)	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:54:33

US3052028
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:01:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:54:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	22 Dec 2020 16:54:33

US3052028
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:01:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	22 Dec 2020 16:54:33

US3052028
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	22 Dec 2020 16:54:33

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User closed query 'Per DM CLR: Please specify the location of Muscle Spasms. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:15:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:35:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:35:05
Data point term sent to Coder	System	29 Mar 2021 16:34:44
Query 'Per DM CLR: Please specify the location of Muscle Spasms. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:34:39
Coding entries removed.		29 Mar 2021 16:34:27
Signature has been broken.		29 Mar 2021 16:34:27
User entered 'MUSCLE SPASMS IN BACK' reason for change: Data Entry Error		29 Mar 2021 16:34:27
User opened query 'Per DM CLR: Please specify the location of Muscle Spasms. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		10 Mar 2021 02:43:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	25 Feb 2021 14:20:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	25 Feb 2021 14:20:53
Data point term sent to Coder	System	25 Feb 2021 14:20:05
User entered 'muscle spasms'	(b) (4), (b) (6)	25 Feb 2021 14:19:27

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:19:27

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 14:19:27

US3052028
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 15:01:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:19:27

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:19:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:19:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	25 Feb 2021 14:19:27

US3052028
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	25 Feb 2021 14:19:27

US3052028

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	25 Feb 2021 14:19:27

US3052028
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 15:01:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	25 Feb 2021 14:19:27

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 17:35:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 17:35:57
Data point term sent to Coder	System	10 Mar 2021 17:35:23
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	10 Mar 2021 17:34:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
User entered 'UN UNK 2010'	(b) (4), (b) (6)	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'Jan 2010'	System	10 Mar 2021 17:34:38

US3052028
Folder: Screening
Form: Medical History (26)
Generated On: 09 Jun 2021 15:01:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '2010'	System	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:01:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	10 Mar 2021 17:34:38

US3052028
Folder: Screening
Form: Medical History (26)
Generated On: 09 Jun 2021 15:01:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered empty.	System	10 Mar 2021 17:34:38

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:31:50
Query 'Per CDM: Please complete this form.' answered with 'Completed.' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	02 Oct 2020 13:53:12
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 11:22:02

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 16:13:00
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Oct 2020 16:13:00
User entered '16:30' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:13:00
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 13:53:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '30 Jul 2020 16:30'	System	06 Oct 2020 16:13:00
User entered empty.	System	02 Oct 2020 13:53:12

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '64.5' in	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12
DataPoint set to visible.	System	30 Jul 2020 22:23:13

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '150' lb	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12
DataPoint set to visible.	System	30 Jul 2020 22:23:13

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered '25.40281'	System	02 Oct 2020 13:53:12
DataPoint set to visible.	System	30 Jul 2020 22:23:13

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'kg/m2'	System	02 Oct 2020 13:53:12
DataPoint set to visible.	System	30 Jul 2020 22:23:13

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:50
User entered '98.4' F	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:30:09
User entered 'Oral (Oral)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:50
User entered '85'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'bpm'	System	02 Oct 2020 13:53:12

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:50
User entered '22'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'breaths/min'	System	02 Oct 2020 13:53:12

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:50
User entered '118'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'mmHg'	System	02 Oct 2020 13:53:12

US3052028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:58:50
User entered '73'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 13:53:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User entered 'mmHg'	System	02 Oct 2020 13:53:12

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29

US3052028
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:07:36

US3052028

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:07:36

Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:01:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:19:26
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:55:14
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 11:09:48
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:01:43
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:01:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:16:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:01:43
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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:19:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:19:11
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:19:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:17:38
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:01:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:01:43
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'not currently employed'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

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 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:01:43
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '1'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

FDA-CBER-2022-1614-0216102

US3052028
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:01:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '0'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

US3052028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:43

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:08:29
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:17:38

Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per CDM: Please complete remaing forms for V1. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:58:48
Query 'Per CDM: Please complete remaing forms for V1. ' answered with 'Completed' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:04:48
User opened query 'Per CDM: Please complete remaing forms for V1. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:00:21
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:50:42

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:50:42

US3052028
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43

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 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	07 Oct 2020 13:40:37
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 13:40:37
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	29 Sep 2020 14:50:42
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:50:42

FDA-CBER-2022-1614-0216107

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'VISIT1'	System	29 Sep 2020 14:50:42

US3052028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:43

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:09:35

US3052028
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:01:43

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:25:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:25:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 21:09:35
User entered '142416' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:09:35

US3052028
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:01:43

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 08:42:39
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Per source documentation, patient is not at risk. ' (Site from System).	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:15:09
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:14:42
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:09:35

US3052028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:43

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 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	27 Oct 2020 20:40:56
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:42:41
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Reviewed and completed. ' (Site from DM).	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:49
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:41
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:49:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:43

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 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:41

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:41

US3052028
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:01:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	27 Oct 2020 20:40:56
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:14:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 20:14:42
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:14:42
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:13:41
User entered empty.	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:41

US3052028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:43

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:13:41

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:01:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '64.5' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '150' lb	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:01:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '64.5' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '150' lb	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:16:15
User entered '30 Jul 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:10:38
User entered '25 Aug 2020'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:16:15
User entered '16:31' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:10:38
User entered '15:18'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '30 Jul 2020 16:31'	System	06 Oct 2020 16:16:15
User entered '25 Aug 2020 15:18'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '98.4' F reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '36.4' C	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '85' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '75'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'bpm'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '22' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '18'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'breaths/min'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '110' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '106'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '73' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '65'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:01:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '64.5' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:01:43
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:00:31
User entered '150' lb	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:16:15
User entered '30 Jul 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:10:38
User entered '25 Aug 2020'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:16:26
User entered '18:30' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:26
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	06 Oct 2020 16:16:15
User entered '16:30' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '16:56'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '30 Jul 2020 18:30'	System	06 Oct 2020 16:16:26
User entered '30 Jul 2020 16:30'	System	06 Oct 2020 16:16:15
User entered '25 Aug 2020 16:56'	System	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '98.2' F reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '98.0' F	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '71' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '70'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'bpm'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '16'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'breaths/min'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '116' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '109'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '72' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:15
User entered '73'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:10:38

US3052028
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	06 Oct 2020 16:10:38

US3052028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:30:26
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:42

US3052028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:30:26
User entered '30 Jul 2020'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:16:42

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

US3052028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

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 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 22:24:01

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '18:01'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

US3052028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '30 Jul 2020 18:01'	System	30 Jul 2020 22:24:01

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Right Arm (RIGHT ARM)'	amy sheets (b) (4) (b) (4)	30 Jul 2020 22:24:01

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'ONCE'	System	30 Jul 2020 22:24:01

US3052028
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:01:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 22:24:01

US3052028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:24

US3052028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:24

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '17:54'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:24

US3052028
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:01:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '30 Jul 2020 17:54'	System	06 Oct 2020 16:17:24

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:01:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '30 Jul 2020'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '17:57'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

FDA-CBER-2022-1614-0216174

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '30 Jul 2020 17:57'	System	06 Oct 2020 16:17:39

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:01:43
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:17:39

US3052028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered empty.	System	06 Oct 2020 16:17:39

US3052028
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:49:16

US3052028
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	25 Aug 2020 20:49:16

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:48:33', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f9a5d39b-3a12-47b8-90be-a51b1b076b9a'	System	30 Jul 2020 22:49:06
User entered 'Yes (Y)'	System	30 Jul 2020 22:49:06

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:48:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f9a5d39b-3a12-47b8-90be-a51b1b076b9a'	System	30 Jul 2020 22:49:06
User entered '98.2'	System	30 Jul 2020 22:49:06

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:48:49', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f9a5d39b-3a12-47b8-90be-a51b1b076b9a'	System	30 Jul 2020 22:49:06
User entered 'No (N)'	System	30 Jul 2020 22:49:06

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:49:02', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f9a5d39b-3a12-47b8-90be-a51b1b076b9a'	System	30 Jul 2020 22:49:06
User entered '30 Jul 2020 18:49'	System	30 Jul 2020 22:49:06

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 18:21'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 20:51'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:26:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0ca12642-7362-4316-99a5-12dba9d6ef85'	System	31 Jul 2020 03:28:02
User entered 'Yes (Y)'	System	31 Jul 2020 03:28:02

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:27:45', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0ca12642-7362-4316-99a5-12dba9d6ef85'	System	31 Jul 2020 03:28:02
User entered '98.6'	System	31 Jul 2020 03:28:02

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:27:51', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0ca12642-7362-4316-99a5-12dba9d6ef85'	System	31 Jul 2020 03:28:02
User entered 'No (N)'	System	31 Jul 2020 03:28:02

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:27:59', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0ca12642-7362-4316-99a5-12dba9d6ef85'	System	31 Jul 2020 03:28:02
User entered '30 Jul 2020 23:27'	System	31 Jul 2020 03:28:02

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 21:46'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 2'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:20:07', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caa05103-bd44-4382-aced-d4a2baa4d34a'	System	01 Aug 2020 04:20:30
User entered 'Yes (Y)'	System	01 Aug 2020 04:20:30

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:20:13', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caa05103-bd44-4382-aced-d4a2baa4d34a'	System	01 Aug 2020 04:20:30
User entered '98.2'	System	01 Aug 2020 04:20:30

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:20:21', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caa05103-bd44-4382-aced-d4a2baa4d34a'	System	01 Aug 2020 04:20:30
User entered 'No (N)'	System	01 Aug 2020 04:20:30

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:20:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caa05103-bd44-4382-aced-d4a2baa4d34a'	System	01 Aug 2020 04:20:30
User entered '01 Aug 2020 00:20'	System	01 Aug 2020 04:20:30

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:24:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 3'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:29:58', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'b336c37a-6a7b-4582-a477-ed3b9cc8a038'	System	02 Aug 2020 02:30:15
User entered 'Yes (Y)'	System	02 Aug 2020 02:30:15

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:03', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'b336c37a-6a7b-4582-a477-ed3b9cc8a038'	System	02 Aug 2020 02:30:15
User entered '97.7'	System	02 Aug 2020 02:30:15

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:08', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'b336c37a-6a7b-4582-a477-ed3b9cc8a038'	System	02 Aug 2020 02:30:15
User entered 'No (N)'	System	02 Aug 2020 02:30:15

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:13', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'b336c37a-6a7b-4582-a477-ed3b9cc8a038'	System	02 Aug 2020 02:30:15
User entered '01 Aug 2020 22:30'	System	02 Aug 2020 02:30:15

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 4'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:20:51', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fec7b382-24a2-4783-8d9f-b24d95ac9b02'	System	03 Aug 2020 02:21:26
User entered 'Yes (Y)'	System	03 Aug 2020 02:21:26

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:21:10', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fec7b382-24a2-4783-8d9f-b24d95ac9b02'	System	03 Aug 2020 02:21:26
User entered '98.4'	System	03 Aug 2020 02:21:26

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:21:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fec7b382-24a2-4783-8d9f-b24d95ac9b02'	System	03 Aug 2020 02:21:26
User entered 'No (N)'	System	03 Aug 2020 02:21:26

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:21:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fec7b382-24a2-4783-8d9f-b24d95ac9b02'	System	03 Aug 2020 02:21:26
User entered '02 Aug 2020 22:21'	System	03 Aug 2020 02:21:26

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 5'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:03:13', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ca031542-f29f-4342-b3d6-635a0a571b35'	System	04 Aug 2020 03:03:54
User entered 'Yes (Y)'	System	04 Aug 2020 03:03:54

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:03:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ca031542-f29f-4342-b3d6-635a0a571b35'	System	04 Aug 2020 03:03:54
User entered '97.9'	System	04 Aug 2020 03:03:54

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:03:48', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ca031542-f29f-4342-b3d6-635a0a571b35'	System	04 Aug 2020 03:03:54
User entered 'No (N)'	System	04 Aug 2020 03:03:54

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:03:50', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ca031542-f29f-4342-b3d6-635a0a571b35'	System	04 Aug 2020 03:03:54
User entered '03 Aug 2020 23:03'	System	04 Aug 2020 03:03:54

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 6'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:09:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fb9869bd-a0c0-4cbb-a13a-ff7cdc080f4f'	System	05 Aug 2020 03:10:28
User entered 'Yes (Y)'	System	05 Aug 2020 03:10:28

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:14', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fb9869bd-a0c0-4cbb-a13a-ff7cdc080f4f'	System	05 Aug 2020 03:10:28
User entered '96.5'	System	05 Aug 2020 03:10:28

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fb9869bd-a0c0-4cbb-a13a-ff7cdc080f4f'	System	05 Aug 2020 03:10:28
User entered 'No (N)'	System	05 Aug 2020 03:10:28

US3052028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:26', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'fb9869bd-a0c0-4cbb-a13a-ff7cdc080f4f'	System	05 Aug 2020 03:10:28
User entered '04 Aug 2020 23:10'	System	05 Aug 2020 03:10:28

Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

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US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 7'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:50:05', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'af348e62-d42f-4c90-a7a4-e030cbf07bb3'	System	30 Jul 2020 22:50:53
User entered 'None (1)'	System	30 Jul 2020 22:50:53

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:50:29', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'af348e62-d42f-4c90-a7a4-e030cbf07bb3'	System	30 Jul 2020 22:50:53
User entered 'No (N)'	System	30 Jul 2020 22:50:53

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:50:33', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'af348e62-d42f-4c90-a7a4-e030cbf07bb3'	System	30 Jul 2020 22:50:53
User entered 'No (N)'	System	30 Jul 2020 22:50:53

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:50:42', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'af348e62-d42f-4c90-a7a4-e030cbf07bb3'	System	30 Jul 2020 22:50:53
User entered 'None (1)'	System	30 Jul 2020 22:50:53

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US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:50:51', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'af348e62-d42f-4c90-a7a4-e030cbf07bb3'	System	30 Jul 2020 22:50:53
User entered '30 Jul 2020 18:50'	System	30 Jul 2020 22:50:53

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 18:21'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 20:51'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:28:14', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '42395ad6-9432-4c88-9422-95b74b992621'	System	31 Jul 2020 03:29:04
User entered 'None (1)'	System	31 Jul 2020 03:29:04

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:28:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '42395ad6-9432-4c88-9422-95b74b992621'	System	31 Jul 2020 03:29:04
User entered 'No (N)'	System	31 Jul 2020 03:29:04

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:28:41', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '42395ad6-9432-4c88-9422-95b74b992621'	System	31 Jul 2020 03:29:04
User entered 'No (N)'	System	31 Jul 2020 03:29:04

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:28:54', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '42395ad6-9432-4c88-9422-95b74b992621'	System	31 Jul 2020 03:29:04
User entered 'None (1)'	System	31 Jul 2020 03:29:04

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:28:59', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '42395ad6-9432-4c88-9422-95b74b992621'	System	31 Jul 2020 03:29:04
User entered '30 Jul 2020 23:28'	System	31 Jul 2020 03:29:04

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 21:46'	System	30 Jul 2020 22:24:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 2'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		04 Mar 2021 14:57:18
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwis clarify.' answered with 'during first safety call subject went over conmeds with caller but did not indicate taking any medications for symptoms documented in the diary' (Site from DM).		03 Mar 2021 22:30:37
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		03 Sep 2020 11:11:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:22:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Aug 2020 04:24:39

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:22:43', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered 'No (N)'	System	01 Aug 2020 04:24:39

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:22:47', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered 'Yes (Y)'	System	01 Aug 2020 04:24:39

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:23:52', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered '1'	System	01 Aug 2020 04:24:39

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:24:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 04:24:39

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:24:34', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6a0272a6-2cc3-446b-9e33-5b32ae488977'	System	01 Aug 2020 04:24:39
User entered '01 Aug 2020 00:24'	System	01 Aug 2020 04:24:39

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 3'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9052f413-6389-4079-8530-aa95f7e146d6'	System	02 Aug 2020 02:31:20
User entered 'None (1)'	System	02 Aug 2020 02:31:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9052f413-6389-4079-8530-aa95f7e146d6'	System	02 Aug 2020 02:31:20
User entered 'No (N)'	System	02 Aug 2020 02:31:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:30:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9052f413-6389-4079-8530-aa95f7e146d6'	System	02 Aug 2020 02:31:20
User entered 'No (N)'	System	02 Aug 2020 02:31:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:13', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9052f413-6389-4079-8530-aa95f7e146d6'	System	02 Aug 2020 02:31:20
User entered 'None (1)'	System	02 Aug 2020 02:31:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9052f413-6389-4079-8530-aa95f7e146d6'	System	02 Aug 2020 02:31:20
User entered '01 Aug 2020 22:31'	System	02 Aug 2020 02:31:20

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 4'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f7d086fa-acfb-4db6-8acd-dc8985d483a4'	System	03 Aug 2020 02:22:22
User entered 'None (1)'	System	03 Aug 2020 02:22:22

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:04', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f7d086fa-acfb-4db6-8acd-dc8985d483a4'	System	03 Aug 2020 02:22:22
User entered 'No (N)'	System	03 Aug 2020 02:22:22

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:08', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f7d086fa-acfb-4db6-8acd-dc8985d483a4'	System	03 Aug 2020 02:22:22
User entered 'No (N)'	System	03 Aug 2020 02:22:22

FDA-CBER-2022-1614-0216276

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:14', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f7d086fa-acfb-4db6-8acd-dc8985d483a4'	System	03 Aug 2020 02:22:22
User entered 'None (1)'	System	03 Aug 2020 02:22:22

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f7d086fa-acfb-4db6-8acd-dc8985d483a4'	System	03 Aug 2020 02:22:22
User entered '02 Aug 2020 22:22'	System	03 Aug 2020 02:22:22

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 5'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:03:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd28e1848-0c4d-483f-8b48-4afd4eb927dd'	System	04 Aug 2020 03:04:18
User entered 'None (1)'	System	04 Aug 2020 03:04:18

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:02', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd28e1848-0c4d-483f-8b48-4afd4eb927dd'	System	04 Aug 2020 03:04:18
User entered 'No (N)'	System	04 Aug 2020 03:04:18

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:05', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd28e1848-0c4d-483f-8b48-4afd4eb927dd'	System	04 Aug 2020 03:04:18
User entered 'No (N)'	System	04 Aug 2020 03:04:18

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:12', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd28e1848-0c4d-483f-8b48-4afd4eb927dd'	System	04 Aug 2020 03:04:18
User entered 'None (1)'	System	04 Aug 2020 03:04:18

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:16', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd28e1848-0c4d-483f-8b48-4afd4eb927dd'	System	04 Aug 2020 03:04:18
User entered '03 Aug 2020 23:04'	System	04 Aug 2020 03:04:18

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 6'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1014815a-c958-4c6f-a2a4-9b806c36cea1'	System	05 Aug 2020 03:11:20
User entered 'None (1)'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1014815a-c958-4c6f-a2a4-9b806c36cea1'	System	05 Aug 2020 03:11:20
User entered 'No (N)'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:10:40', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1014815a-c958-4c6f-a2a4-9b806c36cea1'	System	05 Aug 2020 03:11:20
User entered 'No (N)'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:11:14', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1014815a-c958-4c6f-a2a4-9b806c36cea1'	System	05 Aug 2020 03:11:20
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 03:11:20

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:11:17', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1014815a-c958-4c6f-a2a4-9b806c36cea1'	System	05 Aug 2020 03:11:20
User entered '04 Aug 2020 23:11'	System	05 Aug 2020 03:11:20

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 7'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216301

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:09', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:32', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'None (0)'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered 'No (N)'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T18:51:52', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '760f007e-2863-48bc-bdbb-675f48c09ee6'	System	30 Jul 2020 22:51:55
User entered '30 Jul 2020 18:51'	System	30 Jul 2020 22:51:55

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 18:21'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 20:51'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:05', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

FDA-CBER-2022-1614-0216319

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:26', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:29', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:32', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'None (0)'	System	31 Jul 2020 03:29:51

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:45', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered 'No (N)'	System	31 Jul 2020 03:29:51

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-07-30T23:29:49', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e96b1b6d-f5e1-4b5d-b60b-0c829579036c'	System	31 Jul 2020 03:29:51
User entered '30 Jul 2020 23:29'	System	31 Jul 2020 03:29:51

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Jul 2020 21:46'	System	30 Jul 2020 22:24:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:24:01

FDA-CBER-2022-1614-0216328

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 2'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:02:16
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'during the first safety call the conmeds were reviewed but the subject did not indicate what they took for the symptoms in the diary' (Site from DM).		03 Mar 2021 22:36:33
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		03 Sep 2020 11:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:24:51', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	01 Aug 2020 04:26:24

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:25:06', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'Some interference with activity (2)'	System	01 Aug 2020 04:26:24

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:25:28', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'No interference with activity (1)'	System	01 Aug 2020 04:26:24

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:25:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'None (0)'	System	01 Aug 2020 04:26:24

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:25:49', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'None (0)'	System	01 Aug 2020 04:26:24

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:26:03', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'None (0)'	System	01 Aug 2020 04:26:24

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:26:15', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered 'No (N)'	System	01 Aug 2020 04:26:24

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T00:26:21', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caff1312-763c-4118-a7d9-671747a8eb1c'	System	01 Aug 2020 04:26:24
User entered '01 Aug 2020 00:26'	System	01 Aug 2020 04:26:24

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 3'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:37', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:41', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:50', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:52', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:31:55', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'None (0)'	System	02 Aug 2020 02:32:09

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:32:01', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered 'No (N)'	System	02 Aug 2020 02:32:09

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-01T22:32:06', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '824a4a35-f348-4a1f-80c9-353cb72ff8d8'	System	02 Aug 2020 02:32:09
User entered '01 Aug 2020 22:32'	System	02 Aug 2020 02:32:09

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 4'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:26', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:29', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:33', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:35', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'None (0)'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered 'No (N)'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-02T22:22:47', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '026e08f6-110b-4e52-b28c-767d4448fb5e'	System	03 Aug 2020 02:22:50
User entered '02 Aug 2020 22:22'	System	03 Aug 2020 02:22:50

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 5'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:20', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:31', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:34', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'None (0)'	System	04 Aug 2020 03:04:44

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:40', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered 'No (N)'	System	04 Aug 2020 03:04:44

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-03T23:04:42', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c84bea52-25ed-401b-a9b5-ef36e7b7b93d'	System	04 Aug 2020 03:04:44
User entered '03 Aug 2020 23:04'	System	04 Aug 2020 03:04:44

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 6'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:11:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:11:59', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:11', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:20', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'None (0)'	System	05 Aug 2020 03:12:31

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered 'No (N)'	System	05 Aug 2020 03:12:31

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-04T23:12:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e74344aa-fcdb-4516-ab98-960856c5ccd7'	System	05 Aug 2020 03:12:31
User entered '04 Aug 2020 23:12'	System	05 Aug 2020 03:12:31

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 7'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:24:01

US3052028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	05 Aug 2020 03:11:20
User entered 'Day 8'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-06T22:30:46', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e45f0c7b-a102-4522-bce6-f0f1e0ac5943'	System	07 Aug 2020 02:30:53
User entered 'Yes (Y)'	System	07 Aug 2020 02:30:53

US3052028
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-06T22:30:50', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'e45f0c7b-a102-4522-bce6-f0f1e0ac5943'	System	07 Aug 2020 02:30:53
User entered '06 Aug 2020 22:30'	System	07 Aug 2020 02:30:53

US3052028
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 03:11:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	05 Aug 2020 03:11:20
User entered 'Day 8'	System	05 Aug 2020 03:11:20

FDA-CBER-2022-1614-0216400

US3052028

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-06T22:31:19', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f42e6b31-fbc7-4b07-bede-65f8d074fc7b'	System	07 Aug 2020 02:31:26
User entered 'None (1)'	System	07 Aug 2020 02:31:26

FDA-CBER-2022-1614-0216401

US3052028
Folder: Diary Dose 1 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-06T22:31:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f42e6b31-fbc7-4b07-bede-65f8d074fc7b'	System	07 Aug 2020 02:31:26
User entered '06 Aug 2020 22:31'	System	07 Aug 2020 02:31:26

US3052028

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Open Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 03:11:20

US3052028

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Close Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 03:11:20

US3052028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:52:00

US3052028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '08 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:52:00

US3052028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:52:00

US3052028
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:52:00

US3052028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:49:24

US3052028
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	25 Aug 2020 20:49:24

US3052028
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:08

US3052028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
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).	(b) (4), (b) (6)	08 Oct 2020 08:30:58
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 with 'Confirmed call made 17 AUG 2020' (Site from System).	Avia McClain-Stocker (b) (4)	07 Oct 2020 13:41:52
User entered '17 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 13:41:33
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	29 Sep 2020 14:54:08
User entered '08 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:08

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:08

US3052028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:08

US3052028
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:08

US3052028
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	25 Aug 2020 20:50:08

US3052028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:35

US3052028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 08:48:40
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed call was first attempted and completed on 24 AUG' (Site from System).	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:03:54
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 14:54:35
User entered '24 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:35

FDA-CBER-2022-1614-0216419

US3052028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Sep 2020 14:54:35

US3052028
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:16

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	25 Aug 2020 20:50:16

FDA-CBER-2022-1614-0216422

US3052028
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:27

US3052028
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
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) (6)	27 Aug 2020 11:57:13
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	25 Aug 2020 20:50:27
User entered '25 Aug 2020'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:27

US3052028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

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 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Clinic (Clinic)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:27

US3052028
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'VISIT2'	System	25 Aug 2020 20:50:27

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '25 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '15:18'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '25 Aug 2020 15:18'	System	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '36.4' C	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216432

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Oral (Oral)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216433

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '75'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'bpm'	System	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '18'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'breaths/min'	System	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216438

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '106'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216439

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '65'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216441

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '25 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '16:56'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '25 Aug 2020 16:56'	System	02 Oct 2020 14:26:40

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '98.0' F	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Oral (Oral)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '70'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'bpm'	System	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '16'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

US3052028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'breaths/min'	System	02 Oct 2020 14:26:40

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '109'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

FDA-CBER-2022-1614-0216455

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '73'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:26:40

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:01:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	02 Oct 2020 14:26:40

US3052028
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:01:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '25 Aug 2020'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:50:36

US3052028
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

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 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 20:51:00

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '25 Aug 2020'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '16:26'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '25 Aug 2020 16:26'	System	25 Aug 2020 20:51:00

US3052028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:43

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Right Arm (RIGHT ARM)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:00

US3052028
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'ONCE'	System	25 Aug 2020 20:51:00

US3052028
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:01:43
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 20:51:00

US3052028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:32

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 25AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:41:42
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 25AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'Collection was shipped. ' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 15:04:30
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 25AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:59:22
User entered '25 Aug 2020'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:32

US3052028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '15:36'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '25 Aug 2020 15:36'	System	25 Aug 2020 20:51:32

FDA-CBER-2022-1614-0216474

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '25 Aug 2020'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '15:48'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered '25 Aug 2020 15:48'	System	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:01:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:56

FDA-CBER-2022-1614-0216482

US3052028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
User entered empty.	System	25 Aug 2020 20:51:56

US3052028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Aug 2020 20:51:07

US3052028
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	25 Aug 2020 20:51:07

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-25T16:57:10', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '711e976a-7dfc-4dd7-aeca-fb20a2870382'	System	25 Aug 2020 20:57:35
User entered 'Yes (Y)'	System	25 Aug 2020 20:57:35

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-25T16:57:19', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '711e976a-7dfc-4dd7-aeca-fb20a2870382'	System	25 Aug 2020 20:57:35
User entered '98.0'	System	25 Aug 2020 20:57:35

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-25T16:57:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '711e976a-7dfc-4dd7-aeca-fb20a2870382'	System	25 Aug 2020 20:57:35
User entered 'No (N)'	System	25 Aug 2020 20:57:35

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-25T16:57:31', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '711e976a-7dfc-4dd7-aeca-fb20a2870382'	System	25 Aug 2020 20:57:35
User entered '25 Aug 2020 16:57'	System	25 Aug 2020 20:57:35

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 16:46'	System	25 Aug 2020 20:51:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 19:16'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 20:51:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216494

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216497

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 20:11'	System	25 Aug 2020 20:51:00

FDA-CBER-2022-1614-0216500

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 2'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:28:38', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c87e663c-941e-4b63-bda2-64e28d8e3762'	System	27 Aug 2020 02:29:07
User entered 'Yes (Y)'	System	27 Aug 2020 02:29:07

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:28:50', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c87e663c-941e-4b63-bda2-64e28d8e3762'	System	27 Aug 2020 02:29:07
User entered '99.2'	System	27 Aug 2020 02:29:07

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:28:57', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c87e663c-941e-4b63-bda2-64e28d8e3762'	System	27 Aug 2020 02:29:07
User entered 'No (N)'	System	27 Aug 2020 02:29:07

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:04', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'c87e663c-941e-4b63-bda2-64e28d8e3762'	System	27 Aug 2020 02:29:07
User entered '26 Aug 2020 22:29'	System	27 Aug 2020 02:29:07

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 3'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216512

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 4'	System	25 Aug 2020 20:51:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 5'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 6'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:01:12', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f92572a9-f288-4c14-94e5-4ea558b6a1bd'	System	31 Aug 2020 02:02:16
User entered 'Yes (Y)'	System	31 Aug 2020 02:02:16

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:01:58', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f92572a9-f288-4c14-94e5-4ea558b6a1bd'	System	31 Aug 2020 02:02:16
User entered '94.0'	System	31 Aug 2020 02:02:16

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:03', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f92572a9-f288-4c14-94e5-4ea558b6a1bd'	System	31 Aug 2020 02:02:16
User entered 'No (N)'	System	31 Aug 2020 02:02:16

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:06', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f92572a9-f288-4c14-94e5-4ea558b6a1bd'	System	31 Aug 2020 02:02:16
User entered '30 Aug 2020 22:02'	System	31 Aug 2020 02:02:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 7'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:00:55', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '5068ba9b-ca81-44e4-8f36-f2f535b991c2'	System	01 Sep 2020 02:01:47
User entered 'Yes (Y)'	System	01 Sep 2020 02:01:47

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:01:17', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '5068ba9b-ca81-44e4-8f36-f2f535b991c2'	System	01 Sep 2020 02:01:47
User entered '93.1'	System	01 Sep 2020 02:01:47

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:01:41', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '5068ba9b-ca81-44e4-8f36-f2f535b991c2'	System	01 Sep 2020 02:01:47
User entered 'No (N)'	System	01 Sep 2020 02:01:47

FDA-CBER-2022-1614-0216546

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:01:46', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '5068ba9b-ca81-44e4-8f36-f2f535b991c2'	System	01 Sep 2020 02:01:47
User entered '31 Aug 2020 22:01'	System	01 Sep 2020 02:01:47

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 16:46'	System	25 Aug 2020 20:51:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 19:16'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 20:11'	System	25 Aug 2020 20:51:00

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US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 2'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '25b597ad-26c2-402d-8116-8183ead3182f'	System	27 Aug 2020 02:29:58
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 02:29:58

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:35', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '25b597ad-26c2-402d-8116-8183ead3182f'	System	27 Aug 2020 02:29:58
User entered 'No (N)'	System	27 Aug 2020 02:29:58

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:42', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '25b597ad-26c2-402d-8116-8183ead3182f'	System	27 Aug 2020 02:29:58
User entered 'No (N)'	System	27 Aug 2020 02:29:58

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:53', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '25b597ad-26c2-402d-8116-8183ead3182f'	System	27 Aug 2020 02:29:58
User entered 'None (1)'	System	27 Aug 2020 02:29:58

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-26T22:29:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '25b597ad-26c2-402d-8116-8183ead3182f'	System	27 Aug 2020 02:29:58
User entered '26 Aug 2020 22:29'	System	27 Aug 2020 02:29:58

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 3'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 4'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 5'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 6'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:16', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '746e4dfa-008e-4e90-a739-116037a40277'	System	31 Aug 2020 02:02:38
User entered 'None (1)'	System	31 Aug 2020 02:02:38

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '746e4dfa-008e-4e90-a739-116037a40277'	System	31 Aug 2020 02:02:38
User entered 'No (N)'	System	31 Aug 2020 02:02:38

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '746e4dfa-008e-4e90-a739-116037a40277'	System	31 Aug 2020 02:02:38
User entered 'No (N)'	System	31 Aug 2020 02:02:38

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:32', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '746e4dfa-008e-4e90-a739-116037a40277'	System	31 Aug 2020 02:02:38
User entered 'None (1)'	System	31 Aug 2020 02:02:38

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:36', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '746e4dfa-008e-4e90-a739-116037a40277'	System	31 Aug 2020 02:02:38
User entered '30 Aug 2020 22:02'	System	31 Aug 2020 02:02:38

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

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US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 7'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:01:53', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '96f4b5a1-d378-43c4-bfa5-3eb98b6ad944'	System	01 Sep 2020 02:02:09
User entered 'None (1)'	System	01 Sep 2020 02:02:09

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:01:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '96f4b5a1-d378-43c4-bfa5-3eb98b6ad944'	System	01 Sep 2020 02:02:09
User entered 'No (N)'	System	01 Sep 2020 02:02:09

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '96f4b5a1-d378-43c4-bfa5-3eb98b6ad944'	System	01 Sep 2020 02:02:09
User entered 'No (N)'	System	01 Sep 2020 02:02:09

US3052028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:03', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '96f4b5a1-d378-43c4-bfa5-3eb98b6ad944'	System	01 Sep 2020 02:02:09
User entered 'None (1)'	System	01 Sep 2020 02:02:09

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:07', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '96f4b5a1-d378-43c4-bfa5-3eb98b6ad944'	System	01 Sep 2020 02:02:09
User entered '31 Aug 2020 22:02'	System	01 Sep 2020 02:02:09

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:01:43
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)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 16:46'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 19:16'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

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)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216642

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '25 Aug 2020 20:11'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 2'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:34:24', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'None (0)'	System	27 Aug 2020 05:35:34

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:34:35', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'Some interference with activity (2)'	System	27 Aug 2020 05:35:34

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:34:44', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'Some interference with activity (2)'	System	27 Aug 2020 05:35:34

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:34:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'Some interference with activity (2)'	System	27 Aug 2020 05:35:34

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:35:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 05:35:34

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:35:22', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'None (0)'	System	27 Aug 2020 05:35:34

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:35:26', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered 'No (N)'	System	27 Aug 2020 05:35:34

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:01:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-27T01:35:30', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8104ce19-74da-4bb4-8061-c02202ea7437'	System	27 Aug 2020 05:35:34
User entered '27 Aug 2020 01:35'	System	27 Aug 2020 05:35:34

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 3'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216663

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
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)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 4'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216672

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:01:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 5'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

FDA-CBER-2022-1614-0216683

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:01:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 6'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:49', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:55', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:02:59', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:03:02', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:03:04', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:03:06', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'None (0)'	System	31 Aug 2020 02:03:25

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:03:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered 'No (N)'	System	31 Aug 2020 02:03:25

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-30T22:03:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '9db1549a-df29-4b39-8d99-60c5b947c291'	System	31 Aug 2020 02:03:25
User entered '30 Aug 2020 22:03'	System	31 Aug 2020 02:03:25

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

FDA-CBER-2022-1614-0216699

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	25 Aug 2020 20:51:00
User entered 'Day 7'	System	25 Aug 2020 20:51:00

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:20', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'None (0)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:45', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'Significant; prevents daily activity (3)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:54', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'None (0)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:02:59', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'None (0)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:03:02', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'None (0)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:03:08', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'None (0)'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:03:13', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered 'No (N)'	System	01 Sep 2020 02:03:22

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-08-31T22:03:18', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '17c2b694-d30f-4455-b6fe-969cefa18130'	System	01 Sep 2020 02:03:22
User entered '31 Aug 2020 22:03'	System	01 Sep 2020 02:03:22

US3052028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 20:51:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 20:51:00

FDA-CBER-2022-1614-0216711

US3052028
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	01 Sep 2020 02:03:22
User entered 'Day 8'	System	01 Sep 2020 02:03:22

US3052028

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:43

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-09-01T22:02:23', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0995c8f8-4611-4f06-8044-365d8508cbe6'	System	02 Sep 2020 02:02:29
User entered 'None (0)'	System	02 Sep 2020 02:02:29

US3052028
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:01:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-09-01T22:02:27', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '0995c8f8-4611-4f06-8044-365d8508cbe6'	System	02 Sep 2020 02:02:29
User entered '01 Sep 2020 22:02'	System	02 Sep 2020 02:02:29

US3052028

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 02:03:22

US3052028

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
Data entry locked.	System	01 Sep 2020 02:03:22
User entered 'Day 8'	System	01 Sep 2020 02:03:22

US3052028

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

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)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-09-01T22:02:38', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8f42eab2-b821-4633-8512-465848aac374'	System	02 Sep 2020 02:02:50
User entered 'No (N)'	System	02 Sep 2020 02:02:50

US3052028

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2020-09-01T22:02:46', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8f42eab2-b821-4633-8512-465848aac374'	System	02 Sep 2020 02:02:50
User entered '01 Sep 2020 22:02'	System	02 Sep 2020 02:02:50

US3052028

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 02:03:22

US3052028
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:01:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:04:28
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 02:03:22

US3052028
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:11:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:11:02

FDA-CBER-2022-1614-0216723

US3052028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:11:02

US3052028
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:11:02

US3052028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 16:30:36

US3052028
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	30 Sep 2020 16:30:36

US3052028
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:10:45

US3052028
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:10:45

US3052028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:10:45

US3052028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 17:37:39

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	30 Sep 2020 17:37:39

US3052028
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:28:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '16 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:28:37

US3052028
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:29:01
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:28:37

US3052028
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:29:01
User entered 'left voicemail @ 16:17'	Stacey Saldua (b) (4) (b) (4)	02 Oct 2020 14:28:37

US3052028
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 17:37:53

US3052028
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	30 Sep 2020 17:37:53

US3052028
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:01:52

US3052028
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '29 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:01:52

US3052028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

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 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Clinic (Clinic)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:01:52

US3052028
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'VISIT3'	System	30 Sep 2020 18:01:52

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '29 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '10:20'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '29 Sep 2020 10:20'	System	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Sep 2020 18:08:27
User entered '98.1' F reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Sep 2020 18:08:19
User entered '98.1' (non-conformant).	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Oral (Oral)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '80'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'bpm'	System	30 Sep 2020 18:08:19

FDA-CBER-2022-1614-0216752

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '14'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'breaths/min'	System	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '104'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	30 Sep 2020 18:08:19

US3052028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '71'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:19

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered 'mmHg'	System	30 Sep 2020 18:08:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:52

US3052028
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52

US3052028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:47

US3052028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '29 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:08:47

US3052028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:12:07

US3052028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '29 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:12:07

US3052028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '10:45'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:12:07

US3052028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
User entered '29 Sep 2020 10:45'	System	30 Sep 2020 18:12:07

US3052028
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:12:14

US3052028
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:43
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	30 Sep 2020 18:12:14

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 64'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 71'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0216802

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0216821

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 78'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 92'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

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US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 99'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 106'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered 'Day 113'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 22:24:01

US3052028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:44:32
Data entry locked.	System	30 Jul 2020 22:24:01
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 22:24:01

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (325ad707f3c11b24)', Time: '2021-01-30T00:50:57', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered 'Yes (Y)'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (325ad707f3c11b24)', Time: '2021-01-30T00:51:07', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered 'No (N)'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (325ad707f3c11b24)', Time: '2021-01-30T00:51:38', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered 'No (N)'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (325ad707f3c11b24)', Time: '2021-01-30T00:51:49', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered 'Yes (Y)'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (325ad707f3c11b24)', Time: '2021-01-30T00:52:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (325ad707f3c11b24)', Time: '2021-01-30T00:52:08', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'f1392491-61bb-46c9-8854-92dec74976e1'	System	30 Jan 2021 05:52:18
User entered '30 Jan 2021 00:52:08'	System	30 Jan 2021 05:52:18

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-21T03:27:17', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '53caa108-7c68-4b27-999f-1a51a2034996'	System	21 Feb 2021 08:27:54
User entered 'No (N)'	System	21 Feb 2021 08:27:54

FDA-CBER-2022-1614-0217011

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-21T03:27:25', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '53caa108-7c68-4b27-999f-1a51a2034996'	System	21 Feb 2021 08:27:54
User entered 'No (N)'	System	21 Feb 2021 08:27:54

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-21T03:27:50', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '53caa108-7c68-4b27-999f-1a51a2034996'	System	21 Feb 2021 08:27:54
User entered '21 Feb 2021 03:27:50'	System	21 Feb 2021 08:27:54

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:01:38', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered 'Yes (Y)'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:01:56', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered 'No (N)'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:02:09', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered 'No (N)'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:02:24', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered 'Yes (Y)'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:02:31', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-02-27T00:02:37', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '6dad08bd-bd8b-45d1-ab78-67606e6bbe20'	System	27 Feb 2021 05:08:02
User entered '27 Feb 2021 00:02:37'	System	27 Feb 2021 05:08:02

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:16-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered 'Yes (Y)'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:26-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered 'No (N)'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:32-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered 'No (N)'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:46-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered 'Yes (Y)'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:52-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:41:57-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '4dca6c97-96e4-43c7-9b6f-40e91fea2e22'	System	09 Mar 2021 08:42:06
User entered '09 Mar 2021 03:41:57'	System	09 Mar 2021 08:42:06

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'Yes (Y)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:03:13-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'Yes (Y)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:03:17-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:03:24-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'Yes (Y)'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '1'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '1'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '1'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '1'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '1'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '0'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:04:44-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:05:03-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'Yes (Y)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:05:07-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 05:07:42

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-13T00:05:13-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'ceff4554-0a6e-48d0-a14e-72cd91a11112'	System	13 Mar 2021 05:07:42
User entered '13 Mar 2021 00:05:13'	System	13 Mar 2021 05:07:42

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-20T04:46:37-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1a700ec5-5063-4a8d-abbd-abea74aa08d0'	System	20 Mar 2021 08:46:57
User entered 'No (N)'	System	20 Mar 2021 08:46:57

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-20T04:46:46-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1a700ec5-5063-4a8d-abbd-abea74aa08d0'	System	20 Mar 2021 08:46:57
User entered 'No (N)'	System	20 Mar 2021 08:46:57

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-20T04:46:55-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '1a700ec5-5063-4a8d-abbd-abea74aa08d0'	System	20 Mar 2021 08:46:57
User entered '20 Mar 2021 04:46:55'	System	20 Mar 2021 08:46:57

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-27T00:25:21-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '19424733-7035-48ae-8ccd-0e394812036d'	System	27 Mar 2021 04:26:10
User entered 'No (N)'	System	27 Mar 2021 04:26:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-27T00:25:35-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '19424733-7035-48ae-8ccd-0e394812036d'	System	27 Mar 2021 04:26:10
User entered 'No (N)'	System	27 Mar 2021 04:26:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-27T00:25:42-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '19424733-7035-48ae-8ccd-0e394812036d'	System	27 Mar 2021 04:26:10
User entered '27 Mar 2021 00:25:42'	System	27 Mar 2021 04:26:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:28-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered 'Yes (Y)'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:20-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered 'No (N)'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:18-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered 'No (N)'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:17-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered 'Yes (Y)'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:36-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-03T00:04:52-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'caf74a7b-81d1-4732-83d0-c50ebb3e992f'	System	03 Apr 2021 04:05:10
User entered '03 Apr 2021 00:04:52'	System	03 Apr 2021 04:05:10

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:03:28-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered 'Yes (Y)'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:03:51-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered 'No (N)'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:04:44-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered 'No (N)'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:04:52-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered 'Yes (Y)'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:04:57-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-12T15:05:01-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '40177e0b-d98b-42b1-80e1-df454942b0d6'	System	12 Apr 2021 19:06:22
User entered '12 Apr 2021 15:05:01'	System	12 Apr 2021 19:06:22

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:53:39-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered 'Yes (Y)'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Have you been exposed to someone with 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:53:45-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered 'No (N)'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:53:48-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered 'No (N)'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:53:55-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered 'Yes (Y)'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Please 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 (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:53:58-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-04-19T12:54:01-04:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: 'd840791a-4a31-4c74-bf0a-ae093477047d'	System	19 Apr 2021 16:54:17
User entered '19 Apr 2021 12:54:01'	System	19 Apr 2021 16:54:17

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:44:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:44:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:44:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:44:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0217176

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0217177

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:44:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0217196

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:44:32

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:44:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:44:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:44:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0217255

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:44:32

FDA-CBER-2022-1614-0217286

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:44:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:44:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:44:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:44:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:44:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:01:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:44:32

US3052028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:44:32
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:44:32

US3052028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:01:43

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)	04 May 2021 03:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:42:11-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8d50b0a7-644d-4f99-8ca1-8db265024365'	System	09 Mar 2021 08:42:17
User entered 'No (N)'	System	09 Mar 2021 08:42:17

FDA-CBER-2022-1614-0217329

US3052028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:01:43

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:48:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2BD8540B-5660-48B9-8E12-B41E7645D997)', Time: '2021-03-09T03:42:15-05:00', User OID: 'PatientReportedOutcome (US3052028)', ODM File OID: '8d50b0a7-644d-4f99-8ca1-8db265024365'	System	09 Mar 2021 08:42:17
User entered '09 Mar 2021 03:42:15'	System	09 Mar 2021 08:42:17

US3052028
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	23 Oct 2020 15:16:03

FDA-CBER-2022-1614-0217331

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '22 Oct 2020'	Avia McClain-Stocker (b) (4)	23 Oct 2020 15:16:03

US3052028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	23 Oct 2020 15:16:03

US3052028
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered empty.	Avia McClain-Stocker (b) (4)	23 Oct 2020 15:16:03

US3052028
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	23 Oct 2020 15:16:15

US3052028
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:19
Data entry locked.		03 Apr 2021 20:52:52
User entered '1'	System	23 Oct 2020 15:16:15

US3052028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:25:01

US3052028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:25:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	22 Dec 2020 13:25:01

FDA-CBER-2022-1614-0217339

US3052028
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered 'Left voicemail'	(b) (4), (b) (6)	22 Dec 2020 13:25:01

Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	11 Dec 2020 21:10:53

US3052028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User entered '1'	System	11 Dec 2020 21:10:53

US3052028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User closed query 'Per GCL Lab Reconciliation: Immunogenicity: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 08:38:41
Query 'Per GCL Lab Reconciliation: Immunogenicity: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'the correct draw date is 20FEB2021 and is being corrected in PPD and is also documented in EDC' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:33:09
User opened query 'Per GCL Lab Reconciliation: Immunogenicity: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:39:04
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	31 Dec 2020 20:07:50

US3052028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:42:30
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'the correct draw date is 20FEB2021 and is being corrected in PPD and is also documented in EDC' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:33:14
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 12JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 12:14:40
User entered '26 Dec 2020'	amy sheets (b) (4) (b) (4)	31 Dec 2020 20:07:50

US3052028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User entered 'Contact Made (CONTACT MADE)'	amy sheets (b) (4) (b) (4)	31 Dec 2020 20:07:50

US3052028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User entered empty.	amy sheets (b) (4) (b) (4)	31 Dec 2020 20:07:50

US3052028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	31 Dec 2020 20:07:55

US3052028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User entered '1'	System	31 Dec 2020 20:07:55

US3052028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 14:01:23

FDA-CBER-2022-1614-0217349

US3052028
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
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) (6)	22 Feb 2021 08:34:57
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 'VERIFIED DATE OF CALL' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 14:01:34
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	19 Feb 2021 14:01:23
User entered '13 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 14:01:23

US3052028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:01:23

US3052028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered 'VM FULL'	(b) (4), (b) (6)	19 Feb 2021 14:01:23

US3052028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:22:51

US3052028
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User entered '1'	System	03 Mar 2021 22:22:51

US3052028
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 22:23:23

US3052028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered '2 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:23:23

US3052028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

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 07:51:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:23:23

US3052028
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered 'VISIT4'	System	03 Mar 2021 22:23:23

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '02 Mar 2021'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '14:50'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered '02 Mar 2021 14:50'	System	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '36.8' C	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered 'Oral (Oral)'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered empty.	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '76'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered 'bpm'	System	30 Mar 2021 18:20:21

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 20:45:22
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
Query 'Data is required. Please provide.' answered with 'not collected' (Site from System).	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:29
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 18:20:21
User entered empty.	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered empty.	System	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '111'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered 'mmHg'	System	30 Mar 2021 18:20:21

US3052028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
User entered '74'	amy sheets (b) (4) (b) (4)	30 Mar 2021 18:20:21

US3052028
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:01:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User entered 'mmHg'	System	30 Mar 2021 18:20:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23

US3052028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 22:23:31

US3052028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered '2 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 22:23:31

US3052028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:07:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 22:23:48

US3052028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:07:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:58:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' answered with 'These samples show as received in preclarus. Accession Number: 1F60896 ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 19:53:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:17:07
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered '2 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:23:48

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:07:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered '15:19'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:23:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:07:17
User entered '2 Mar 2021 15:19'	System	03 Mar 2021 22:23:48

US3052028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:23:51

US3052028
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:01:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:17
User entered '1'	System	03 Mar 2021 22:23:51

US3052028
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:13:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:23
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:13:03

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Mar 2021 18:13:03

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User closed query 'Per DM CLR: Review specified comment, SUBJECT REPORTED UNDERGOING A CHOLECYSTECTOMY DUE TO CHOLECYSTITIS THAT OCCURRED 10MAR2021. Verify if this condition (Cholecystitis) meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).		16 Apr 2021 16:52:44
Query 'Per DM CLR: Review specified comment, SUBJECT REPORTED UNDERGOING A CHOLECYSTECTOMY DUE TO CHOLECYSTITIS THAT OCCURRED 10MAR2021. Verify if this condition (Cholecystitis) meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'AE will be documented ' (Site from DM).		14 Apr 2021 13:12:22
User opened query 'Per DM CLR: Review specified comment, SUBJECT REPORTED UNDERGOING A CHOLECYSTECTOMY DUE TO CHOLECYSTITIS THAT OCCURRED 10MAR2021. Verify if this condition (Cholecystitis) meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).		03 Apr 2021 16:44:37
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:23
User entered 'Subject reported undergoing a cholecystectomy due to cholecystitis that occurred 10MAR2021'	(b) (4), (b) (6)	26 Mar 2021 18:13:03

US3052028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 20:39:06

US3052028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered '1'	System	26 Mar 2021 20:39:06

US3052028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	28 Apr 2021 12:26:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 13:11:30

US3052028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

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 18:39:54
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	28 Apr 2021 12:26:17
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) (6)	27 Apr 2021 13:11:34
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 13:11:30
User entered '26 Apr 2021'	(b) (4), (b) (6)	27 Apr 2021 13:11:30

US3052028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	28 Apr 2021 12:26:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	27 Apr 2021 13:11:30

US3052028
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:01:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	28 Apr 2021 12:26:17
User entered 'LEFT VOICEMAIL'	(b) (4), (b) (6)	27 Apr 2021 13:11:30

US3052028

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	28 Apr 2021 12:26:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 13:11:38

US3052028

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:43

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 13:11:38

US3052028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:31:00

US3052028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:47:09
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 22:21:25
User entered '23 Jan 2021' reason for change: Data Entry Error		03 Mar 2021 22:21:25
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered '20 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 13:31:00

US3052028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:43

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Feb 2021 13:31:00

US3052028
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:01:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 13:31:00

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:07:09

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:07:09

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 16:22:25
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 15:10:16
User closed query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' (Site from DM).		12 Apr 2021 15:01:46
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'data entry error, corrected' (Site from System).		08 Apr 2021 15:19:22
Query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' answered with 'corrected' (Site from DM).		08 Apr 2021 15:18:40
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 15:17:46
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 15:17:46
User entered '12 Jan 2021' reason for change: Data Entry Error		08 Apr 2021 15:17:46
User opened query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' (Site from DM).		08 Apr 2021 07:40:07
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).		01 Mar 2021 17:57:43
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'subject was unblinded via telephone 1/23/21 and completed DV on site 2/20/21' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 13:33:50
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	25 Feb 2021 13:32:57
User entered '23 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 13:32:57

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered empty.	System	25 Feb 2021 13:32:57

US3052028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:43

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered empty.	System	25 Feb 2021 13:32:57

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 13:34:23

FDA-CBER-2022-1614-0217411

US3052028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User closed query 'Per GCL Lab Recon: Immuno: Thank you for the response, however per latest Preclarus report the samples are reflecting as still "missing in PPD GCL" records. Please kindly review and confirm in the response if the samples have been received at PPD GCL or if they are lost in transit. Please kindly keep this query open, till it is resolved.Thank you. ' (Site from DM).		30 Mar 2021 11:54:41
Query 'Per GCL Lab Recon: Immuno: Thank you for the response, however per latest Preclarus report the samples are reflecting as still "missing in PPD GCL" records. Please kindly review and confirm in the response if the samples have been received at PPD GCL or if they are lost in transit. Please kindly keep this query open, till it is resolved.Thank you. ' answered with 'all samples have been shipped and responses provided in preclarus. please let us know if received.' (Site from DM).	amy sheets (b) (4) (b) (4)	23 Mar 2021 16:22:55
User opened query 'Per GCL Lab Recon: Immuno: Thank you for the response, however per latest Preclarus report the samples are reflecting as still "missing in PPD GCL" records. Please kindly review and confirm in the response if the samples have been received at PPD GCL or if they are lost in transit. Please kindly keep this query open, till it is resolved.Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:25:36
User closed query 'Per GCL lab Recon:"OL-D1" Immuno sample dated 20 FEB 2021 is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample.Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:25:36
Query 'Per GCL lab Recon:"OL-D1" Immuno sample dated 20 FEB 2021 is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample.Thank you.' answered with 'the req has been scanned to preclarus' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Mar 2021 20:46:06

US3052028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per GCL lab Recon:"OL-D1" Immuno sample dated 20 FEB 2021 is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:45:02
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '20 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 13:34:23

US3052028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '15:32'	(b) (4), (b) (6)	25 Feb 2021 13:34:23

US3052028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered '20 Feb 2021 15:32'	System	25 Feb 2021 13:34:23

US3052028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:34:51

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:01:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "REQ. WAS EMAILED TO PPD. COLLECTION DATE IS CORRECT"; however, kindly consider providing accession, tracking number & shipped date for swab sample collected on 20-FEB-2021 as the sample is missing in Preclarus, else clarify. ' (Site from DM).		23 Apr 2021 04:25:58
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "REQ. WAS EMAILED TO PPD. COLLECTION DATE IS CORRECT"; however, kindly consider providing accession, tracking number & shipped date for swab sample collected on 20-FEB-2021 as the sample is missing in Preclarus, else clarify. ' answered with 'UPDATED' (Site from DM).		13 Apr 2021 16:53:15
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "REQ. WAS EMAILED TO PPD. COLLECTION DATE IS CORRECT"; however, kindly consider providing accession, tracking number & shipped date for swab sample collected on 20-FEB-2021 as the sample is missing in Preclarus, else clarify. ' (Site from DM).		07 Apr 2021 12:08:39
User closed query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "20FEB2021" for Participant Decision Visit / OL-D1, please review and confirm the sample collection date. In Preclarus report, for the subject US3052028 sample collection date is recorded as 12JAN2020 with accession number " 1F600086621" and Requisition kit id "1F600077015". Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).		07 Apr 2021 12:08:39

US3052028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "20FEB2021" for Participant Decision Visit / OL-D1, please review and confirm the sample collection date. In Preclarus report, for the subject US3052028 sample collection date is recorded as 12JAN2020 with accession number " 1F600086621" and Requisition kit id "1F600077015". Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'REQ. WAS EMAILED TO PPD. COLLECTION DATE IS CORRECT' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:35:43
User opened query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "20FEB2021" for Participant Decision Visit / OL-D1, please review and confirm the sample collection date. In Preclarus report, for the subject US3052028 sample collection date is recorded as 12JAN2020 with accession number " 1F600086621" and Requisition kit id "1F600077015". Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:31:58
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 20FEB2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:31:58

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 20FEB2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'the req has been scanned to preclarus and shipped ' (Site from DM).	amy sheets (b) (4) (b) (4)	10 Mar 2021 20:45:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 20FEB2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:43:56
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '20 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 13:34:51

US3052028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:43

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '15:34'	(b) (4), (b) (6)	25 Feb 2021 13:34:51

US3052028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:43

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:40
User entered '20 Feb 2021 15:34'	System	25 Feb 2021 13:34:51

US3052028
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:01:43

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:37
User closed query 'Per CDM CLR re-query: Per response however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).		25 Apr 2021 01:41:35
User closed query 'Per CDM CLR Re-query: Per response however there is no change reflecting in the eCRF, kindly review the AE page and amend as appropriate.' (Site from DM).		25 Apr 2021 01:41:32
Query 'Per CDM CLR re-query: Per response however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' answered with 'AE's have been updated per safety follow up with subject' (Site from DM).		22 Apr 2021 20:00:14
Query 'Per CDM CLR Re-query: Per response however there is no change reflecting in the eCRF, kindly review the AE page and amend as appropriate.' answered with 'This query :"'Per DM CLR: Per Day 229 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification." is reflective of dates MARCH 13-17 2021 and has been answered with an AE added to Adverse events' (Site from DM).		19 Apr 2021 17:50:32
User opened query 'Per CDM CLR re-query: Per response however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).		16 Apr 2021 06:35:13
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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).		16 Apr 2021 06:35:13

US3052028
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:01:43
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per CDM CLR Re-query: Per response however there is no change reflecting in the eCRF, kindly review the AE page and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:32:05
User closed query 'Per DM CLR: Per Day 229 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:32:05
Query 'Per DM CLR: Per Day 229 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'AE has since been updated and medical records pending' (Site from DM).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:40:08
Query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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 'AE has since been updated and medical records pending' (Site from DM).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:39:39
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, 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)	02 Apr 2021 15:50:53

FDA-CBER-2022-1614-0217423

US3052028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:01:43

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Day 229 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 03:38:14
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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 00:53:07
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, 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' (Site from DM).	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:22:38
User opened query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, 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)	24 Mar 2021 06:24:03
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:11:14

US3052028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:01:43

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 11:56:05

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:22:10
Un-reviewed for Safety.		07 Apr 2021 12:22:03
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:28:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'USA-US117-2020-mRNA-1273-P301000001'	System	06 Aug 2020 15:03:22
User entered 'New'	(b) (4), (b) (6)	06 Aug 2020 15:03:22

US3052028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per CDM: per sponsor review, please advise if chest pain is related to cardiac or non-cardiac and update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:58:17
Query 'Per CDM: per sponsor review, please advise if chest pain is related to cardiac or non-cardiac and update accordingly.' answered with 'unknown' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 14:05:54
User opened query 'Per CDM: per sponsor review, please advise if chest pain is related to cardiac or non-cardiac and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:50:26
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:38:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:38:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:23:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:23:07
Data point term sent to Coder	System	19 Nov 2020 19:22:32
User closed query 'CDM Coding: Kindly update the term as 'Chest Pain NOS' as per the query response.' (Site from System).	System	19 Nov 2020 19:22:18
Query 'CDM Coding: Kindly update the term as 'Chest Pain NOS' as per the query response.' answered with 'update the term per query response' (Site from System).	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:22:18
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:22:08
Coding entries removed.	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:22:08
User entered 'CHEST PAIN NOS' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:22:08

US3052028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
User opened query 'CDM Coding: Kindly update the term as 'Chest Pain NOS' as per the query response.' (Site from System).	Coder Import (b) (4) (b) (4)	13 Nov 2020 09:32:42
User closed query 'PV Query: The event term 'chest pain- GI intolerance to brown rice' contains multiple event terms. Please consider separating them into separate events. Please consider providing the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:33:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
Data point term sent to Coder	System	11 Nov 2020 15:32:57
User closed query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	11 Nov 2020 15:31:56
Query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'Chest Pain Unknown in etiology' (Site from System).	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:31:56
User opened query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:03:45
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:38:41
Data point term sent to Coder	System	10 Nov 2020 18:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
User entered 'Chest Pain' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
Data point term sent to Coder	System	10 Nov 2020 17:23:49
Query 'PV Query: The event term 'chest pain- GI intolerance to brown rice' contains multiple event terms. Please consider separating them into separate events. Please consider providing the final diagnosis.' answered with 'Changed Information per query. ' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:23:43
User entered 'GI INTOLERANCE TO BROWN RICE.' reason for change: Per Query Resolution	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:23:07
Data point term sent to Coder	System	10 Nov 2020 17:21:46
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	10 Nov 2020 17:21:03
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'Medical Records will be request to determine etiology. ' (Site from System).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:21:03
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' canceled (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:19:34
User opened query 'PV Query: The event term 'chest pain- GI intolerance to brown rice' contains multiple event terms. Please consider separating them into separate events. Please consider providing the final diagnosis.' (Site from Safety).		15 Oct 2020 16:18:33
Data point term sent to Coder	System	08 Oct 2020 14:57:58
Coding entries removed.	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User entered 'CHEST PAIN- GI intolerance to brown rice.' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:14:20
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Aug 2020 19:44:45
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:11:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 13:11:14
Data point term sent to Coder	System	06 Aug 2020 13:10:20
User entered 'Chest Pain'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

FDA-CBER-2022-1614-0217430

US3052028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

US3052028
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:01:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'No (N)'		06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User closed query 'Per CDM: Please provide' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:49:34
DataPoint Verified.		11 Nov 2020 16:29:06
Query 'Per CDM: Please provide' answered with 'Information is correct. ' (Site from DM).	Stacey Saldua (b) (4)	10 Nov 2020 17:24:14
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	08 Oct 2020 14:57:40
	(b) (4)	
User opened query 'Per CDM: Please provide' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:50:47
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:25:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).		09 Sep 2020 11:42:07
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	25 Aug 2020 20:51:00
User entered '05 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered empty.		06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per CDM : Please note the outcome is recovered/Resolved but Ongoing is answered as "Yes".Kindly confirm if ongoing is "YES" , if yes kindly update the outcome. If ongoing is "No", provide end date .Thanks ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:53:23
Query 'Per CDM : Please note the outcome is recovered/Resolved but Ongoing is answered as "Yes".Kindly confirm if ongoing is "YES" , if yes kindly update the outcome. If ongoing is "No", provide end date .Thanks ' answered with 'updated. please review' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:40:47
User entered 'No (N)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:40:08
User opened query 'Per CDM : Please note the outcome is recovered/Resolved but Ongoing is answered as "Yes".Kindly confirm if ongoing is "YES" , if yes kindly update the outcome. If ongoing is "No", provide end date .Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 04:42:38
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:25:12
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:23:28
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:23:28
User entered 'Yes (Y)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:23:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'No (N)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '06 Aug 2020' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:40:08
User closed query 'Per CDM: Thank you for your response "ONGOING", please reconcile as Ongoing? has been answered as "No". ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 04:40:38
Query 'Per CDM: Thank you for your response "ONGOING", please reconcile as Ongoing? has been answered as "No". ' answered with 'Reconcile to as ongoing per query' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:26:22
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:25:12
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	19 Nov 2020 19:25:12
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 20:51:54
User opened query 'Per CDM: Thank you for your response "ONGOING", please reconcile as Ongoing? has been answered as "No". ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:51:52
Un-reviewed for Data Management.		16 Nov 2020 20:49:41
Reviewed for Data Management.		16 Nov 2020 20:49:36
DataPoint Verified.		11 Nov 2020 16:29:06
User entered '06 Aug 2020' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'Ongoing. ' (Site from System).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:24:46
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	08 Oct 2020 14:57:40
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:35:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	10 Nov 2020 18:38:15
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:38:15
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	10 Nov 2020 18:37:41
User entered '12:43' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing.' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:24:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Aug 2020 19:46:33
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 18:38:15
User entered '06 Aug 2020 12:43'	System	10 Nov 2020 18:37:41
User entered empty.	System	06 Aug 2020 13:10:16

US3052028
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:01:43
Severity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:28:56
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:50:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Per Query Resolution	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
Query 'PV Query: Please provide intensity scale for event.' canceled (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:20:16
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 14:57:40
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User opened query 'PV Query: Please provide intensity scale for event.' (Site from Safety).	(b) (4), (b) (6)	11 Aug 2020 19:47:12
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 13:10:16
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Nov 2020 14:08:55
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Nov 2020 13:32:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Nov 2020 18:39:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Nov 2020 18:37:41
User entered 'Yes (Y)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
User entered 'No (N)' reason for change: Per Query Resolution	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'		06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

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Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'		06 Aug 2020 13:10:16

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Form: Adverse Events (1)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:07:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 11:54:13
User entered '1' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 14:08:55
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'patient was kept overnight for observation' (Site from System).	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:35:25
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'subject was hospitalized overnight for observation' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:35:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:32:38
User entered '0' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:32:38
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:01:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06

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Form: Adverse Events (1)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Nov 2020 18:39:28
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 18:39:28
User entered '1' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:39:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Nov 2020 18:37:41
User entered '0' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 14:57:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Oct 2020 14:57:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Aug 2020 13:10:16
User entered '1'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '05 Aug 2020' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User entered '05 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Form: Adverse Events (1)

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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '06 Aug 2020' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User entered '06 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'No (N)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:37:41
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Form: Adverse Events (1)
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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) **(b) (4), (b) (6)**	11 Nov 2020 16:29:06
User entered empty.		06 Aug 2020 13:10:16

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'		06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'		06 Aug 2020 13:10:16

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Form: Adverse Events (1)

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'		06 Aug 2020 13:10:16

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Folder: Adverse Events
Form: Adverse Events (1)
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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered 'Not Related (NOT RELATED)'		06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

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Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 14:57:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 13:10:16
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
Query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge.' canceled (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:20:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 14:57:40
User entered 'None (NONE)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User opened query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge.' (Site from Safety).	(b) (4), (b) (6)	11 Aug 2020 19:47:33
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 13:10:16
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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None

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 16:22:54
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Mar 2021 16:20:31
DataPoint Un-verified.	amy sheets (b) (4) (b) (4)	23 Mar 2021 16:20:31
Signature has been broken.	amy sheets (b) (4) (b) (4)	23 Mar 2021 16:20:31
User entered '0' reason for change: New Information	amy sheets (b) (4) (b) (4)	23 Mar 2021 16:20:31
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Mar 2021 16:20:15
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:34:46
Signature has been broken.	Avia McClain-Stocker (b) (4)	17 Mar 2021 20:30:20
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User closed query 'Per CDM, per DM CLR re-query: Response " Information has been changed not Hospitalization" is noted; however "Requires inpatient or prolongation of existing Hospitalization" is selected and and hospital data is provided. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:52:31
Query 'Per CDM, per DM CLR re-query: Response " Information has been changed not Hospitalization" is noted; however "Requires inpatient or prolongation of existing Hospitalization" is selected and and hospital data is provided. Kindly update as appropriate or clarify.' answered with 'updated. please review and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	30 Nov 2020 13:35:58
User opened query 'Per CDM, per DM CLR re-query: Response " Information has been changed not Hospitalization" is noted; however "Requires inpatient or prolongation of existing Hospitalization" is selected and and hospital data is provided. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:35:49

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None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:35:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Information has been changed not Hospitalization ' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:29:27
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 17:28:57
User entered '1' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:28:57
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:50:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Aug 2020 13:10:16
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 20:28:51
DataPoint Un-verified.	(b) (4) amy sheets (b) (4)	23 Mar 2021 16:20:15
Signature has been broken.	(b) (4) amy sheets (b) (4)	23 Mar 2021 16:20:15
User entered '1' reason for change: Data Entry Error	(b) (4) amy sheets (b) (4)	23 Mar 2021 16:20:15
User signature succeeded.	(b) (4) Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:06
Query 'Per ETRTR: Please confirm after receiving details, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:25
User opened query 'Per ETRTR: Please confirm after receiving details, thanks.' (Site from CRA).		07 Aug 2020 17:25:24
User entered '0'		06 Aug 2020 13:10:16

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
Signature has been broken.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:10:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events
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Outcome

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4) **(b) (4), (b) (6)**	11 Nov 2020 16:29:06
Query 'PV query: Please provide the final outcome, when available.' canceled (Site from Safety).		15 Oct 2020 16:19:54
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 14:57:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 14:57:40
User opened query 'PV query: Please provide the final outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	11 Aug 2020 19:46:47
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 13:10:16
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:29:06
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Once available, please provide the findings of the colonoscopy. Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:08:11
Query 'PV Query: Once available, please provide the findings of the colonoscopy. Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history.' answered with 'subject still has not been seen for a colonoscopy' (Site from Safety).		03 Mar 2021 22:35:21
User opened query 'PV Query: Once available, please provide the findings of the colonoscopy. Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history.' (Site from Safety).		26 Feb 2021 20:53:33
User closed query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' (Site from Safety).		26 Feb 2021 20:53:29
User closed query 'Per DM CLR: Narrative indicates that the subject was given Nitroglycerin that relieved the pain. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).		26 Feb 2021 10:47:03
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Query 'Per DM CLR: Narrative indicates that the subject was given Nitroglycerin that relieved the pain. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:31:13
Query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' answered with 'colonoscopy has not yet occured' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:29:06

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the etiology of the chest pain.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 21:29:07
User closed query 'PV Query: Please confirm if the subject was tested for COVID-19. If yes, please provide results. If no, please confirm in query response.' (Site from Safety).		22 Dec 2020 21:29:05
Query 'PV Query: Please confirm if the subject was tested for COVID-19. If yes, please provide results. If no, please confirm in query response.' answered with 'test given @ 1548 on 8/25/20 with a negative result.' (Site from Safety).		22 Dec 2020 17:07:14
Query 'PV Query: Please provide the etiology of the chest pain.' answered with 'unknown' (Site from Safety).		22 Dec 2020 17:05:09
User opened query 'Per DM CLR: Narrative indicates that the subject was given Nitroglycerin that relieved the pain. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).		20 Nov 2020 20:08:10
User opened query 'PV Query: Please provide the etiology of the chest pain.' (Site from Safety).		20 Nov 2020 17:02:08
User opened query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' (Site from Safety).		20 Nov 2020 17:01:15
User opened query 'PV Query: Please confirm if the subject was tested for COVID-19. If yes, please provide results. If no, please confirm in query response.' (Site from Safety).		20 Nov 2020 17:00:16
User closed query 'PV query: Was a cardiology work-up done? If so, please provide results' (Site from Safety).		11 Nov 2020 21:34:49
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		11 Nov 2020 21:34:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		11 Nov 2020 21:34:31

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:01:43
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:34:26
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		11 Nov 2020 21:34:17
User closed query 'PV Query: Was the patient seen in consultation by cardiology? If so, please provide their assessment.' (Site from Safety).		11 Nov 2020 21:34:08
User closed query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' (Site from Safety).		11 Nov 2020 21:34:01
DataPoint Verified.		11 Nov 2020 16:29:06
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 18:48:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 18:48:14
User entered 'Patient was presented with stabbing chest pain that radiates laterally from her sternum. The pain lasted 30 minutes until she was given Nitroglycerin by EMS. The nitroglycerin stopped her pain. Nothing made the pain worse, no shortness of breath.' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 18:48:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 18:37:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' answered with 'Medical Records will be requested' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:31:47
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'None' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:31:22
Query 'PV Query: Was the patient seen in consultation by cardiology? If so, please provide their assessment.' answered with 'No' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:31:15
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Not Applicable ' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:31:05
Query 'PV query: Was a cardiology work-up done? If so, please provide results' answered with 'Not Applicable ' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:30:51
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'none' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:30:32
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'None' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	10 Nov 2020 17:30:21
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 17:28:57
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 17:28:57
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:20:40

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US3052028
Folder: Adverse Events
Form: Adverse Events (1)
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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide further detail regarding the 'mass colon requiring colonoscopy pending" as reported in the medical history. What was the finding at the colonoscopy?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:18:46
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		11 Aug 2020 19:50:19
User opened query 'PV Query: Was the patient seen in consultation by cardiology? If so, please provide their assessment.' (Site from Safety).		11 Aug 2020 19:50:01
User opened query 'PV query: Was a cardiology work-up done? If so, please provide results' (Site from Safety).		11 Aug 2020 19:49:44
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		11 Aug 2020 19:49:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		11 Aug 2020 19:49:08
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		11 Aug 2020 19:48:50
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		11 Aug 2020 19:48:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Aug 2020 13:10:16
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 13:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 18:37:41
User entered '0'	System	10 Nov 2020 17:28:57
Amendment Manager: User entered '1'	System	21 Aug 2020 01:25:56
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:25:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 01:25:56
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:25:54

US3052028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 14:57:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:25:54

US3052028
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 07:36:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 07:36:52
Data point term sent to Coder	System	24 Mar 2021 22:22:02
User entered 'abdominal pain following surgery'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '11 Mar 2021'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

US3052028
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User entered empty.	System	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '12 Mar 2021'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User entered empty.	System	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:01:43

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 19:34:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 19:34:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:34:12
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 22:21:43
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 19:34:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 19:34:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:34:12
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 22:21:43
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Not Applicable (NOT APPLICABLE)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 19:44:02
User entered '1' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:44:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 22:21:43
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Form: Adverse Events (4)

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:21:43

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Folder: Adverse Events

Form: Adverse Events (4)

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User entered '0'	System	24 Mar 2021 22:21:43

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Form: Adverse Events (4)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50
User entered '0'	System	24 Mar 2021 22:21:43

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Form: Adverse Events (4)

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Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:19:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

AEID

Audit	User	Time (GMT)
Un-reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 11:56:40
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 20:28:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:07
Un-reviewed for Safety.		07 Apr 2021 12:22:03
Reviewed for Safety.		07 Apr 2021 12:21:56
User entered 'USA-US117-2021-mRNA-1273-P301000006'	System	05 Apr 2021 13:12:52
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 13:12:52

US3052028
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:01:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User closed query 'Per CDM RQ: Thank you for your response indicating the chest pain is 'Musculoskeletal'. Please agree to add this to the AE term.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:57:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 20:30:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 20:30:09
Data point term sent to Coder	System	30 Apr 2021 20:29:04
Query 'Per CDM RQ: Thank you for your response indicating the chest pain is 'Musculoskeletal'. Please agree to add this to the AE term.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 20:28:17
Coding entries removed.		30 Apr 2021 20:28:09
User entered 'Musculoskeletal CHEST PAIN' reason for change: Data Entry Error		30 Apr 2021 20:28:09
User opened query 'Per CDM RQ: Thank you for your response indicating the chest pain is 'Musculoskeletal'. Please agree to add this to the AE term.' (Site from DM).		30 Apr 2021 20:00:52
User closed query 'Per MM, please update event term to reflect if this chest pain is muskuloskeletal or cardiac related ' (Site from DM).		29 Apr 2021 18:13:00
Query 'Per MM, please update event term to reflect if this chest pain is muskuloskeletal or cardiac related ' answered with 'MUSCULOSKELETAL' (Site from DM).		27 Apr 2021 13:48:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 12:37:00

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Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 12:37:00
Data point term sent to Coder	System	27 Apr 2021 12:36:20
User entered 'CHEST PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 12:35:42
Data point term sent to Coder		27 Apr 2021 12:35:20
Coding entries removed.		27 Apr 2021 12:35:08
Signature has been broken.		27 Apr 2021 12:35:08
User entered 'CHEST PAINi' reason for change: Data Entry Error		27 Apr 2021 12:35:08
User opened query 'Per MM, please update event term to reflect if this chest pain is muskuloskeletal or cardiac related ' (Site from DM).		25 Apr 2021 21:30:54
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 13:46:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 13:46:30
Data point term sent to Coder	System	03 Apr 2021 13:45:14
User entered 'Chest Pain'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Yes (Y)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:01:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '03 Apr 2021'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

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Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

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AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Apr 2021 13:44:17

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Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User entered 'Yes (Y)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:19:11
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:31
User entered '04 Apr 2021' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:47:14
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:01:43

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

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Severity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:51:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events
Form: Adverse Events (5)
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Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	03 Apr 2021 13:45:18
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	03 Apr 2021 13:44:17
User entered 'Yes (Y)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Form: Adverse Events (5)

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Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:02:35
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Apr 2021 13:45:18
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	03 Apr 2021 13:45:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Apr 2021 13:45:18
User entered '1' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Apr 2021 13:44:17
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

Folder: Adverse Events

Form: Adverse Events (5)

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '03 Apr 2021'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update this date if available else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:55:56
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
Query 'Per CDM: Please update this date if available else clarify.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:46
User entered '04 Apr 2021' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User opened query 'Per CDM: Please update this date if available else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 20:03:48
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'No (N)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:28:01
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:45:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 13:45:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:44:17
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:45:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 13:45:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:44:17
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 20:28:51
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:32:31
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated' (Site from DM).		14 Apr 2021 15:13:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		14 Apr 2021 14:53:14
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).		10 Apr 2021 06:18:34
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:45:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 13:45:18
User entered 'None (NONE)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:44:17
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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None

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Apr 2021 13:45:18
User entered '1' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:18
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Apr 2021 13:44:17
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '1' reason for change: Data Entry Error amy sheets (b) (4) (b) (4)		15 Apr 2021 19:29:12
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered '0'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Outcome

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:19:24
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:30:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:48:04
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:45:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 13:45:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:45:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 13:44:17
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: When records become available, please provide treatment information including intravenous fluids, antibiotics, and breathing treatment details. ' answered with 'MEDICATIONS WERE UPDATED' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:40:23
Query 'PV Query: Thank you for confirming medical records have been requested. When available, please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'MEDICAL RECORDS WERE SENT TO THE Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:40:17
User opened query 'PV Query: When records become available, please provide treatment information including intravenous fluids, antibiotics, and breathing treatment details. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:37:05
User opened query 'PV Query: Thank you for confirming medical records have been requested. When available, please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:36:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:20:04
User closed query 'PV Query: Oral nitroglycerine use on 05Aug2020 for chest pain was reported in eCRF. Did the subject have history of coronary artery disease and/or chest pain? If yes, please add to medical history in eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:19:50

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:19:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:19:29
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 20:28:51
Query 'PV Query: Oral nitroglycerine use on 05Aug2020 for chest pain was reported in eCRF. Did the subject have history of coronary artery disease and/or chest pain? If yes, please add to medical history in eCRF accordingly.' answered with 'no this was a different AE ' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:38:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records requested' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:37:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records requested' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:36:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:30:53

US3052028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Narrative

Audit	User	Time (GMT)
User entered 'subject admitted to the hospital per the patient she was given IV fluids, antibiotics, and breathing tx. her records have been requested.' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	15 Apr 2021 19:29:12
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:49:21
User opened query 'PV Query: Oral nitroglycerine use on 05Aug2020 for chest pain was reported in eCRF. Did the subject have history of coronary artery disease and/or chest pain? If yes, please add to medical history in eCRF accordingly.' (Site from Safety).		13 Apr 2021 17:48:38
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		13 Apr 2021 17:48:19
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		13 Apr 2021 17:47:29
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL. MEDICAL RECORDS TO FOLLOW.' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:46:33
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL. MEDICAL RECORDS TO FOLLOW'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:44:17

US3052028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 13:44:17

US3052028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 13:44:17

US3052028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	03 Apr 2021 13:44:17

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:01:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:37
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:47:09
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:56:32
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'during first safety call subject went over conmeds with caller but did not indicate taking any medications for symptoms documented in the diary' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:31:06
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:21:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:29
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:55:19

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:49:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:49:38
Data point term sent to Coder	System	15 Oct 2020 19:57:10
User entered 'GLIPIZIDE'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'DIABETES MILITUS'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '10'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'mg (mg)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:01:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'twice daily (BID)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:57:27
User entered 'UN UNK 2008' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:27
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:57:05
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '0'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:57:05

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:30:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:30:23
Data point term sent to Coder	System	15 Oct 2020 20:01:19
User entered 'PIOGLIPIZIDE'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'DIABETES MILLITUS'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '10'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'mg (mg)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'four times daily (QID)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'UN UNK 2008'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '0'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 20:00:34

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:15:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:15:53
Data point term sent to Coder	System	25 Feb 2021 14:14:52
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 14:14:44
Coding entries removed.		25 Feb 2021 14:14:44
Signature has been broken.		25 Feb 2021 14:14:44
User entered 'levothyroxine' reason for change: Dat Entry Error		25 Feb 2021 14:14:44
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:05:28
Data point term sent to Coder	System	15 Oct 2020 20:04:31
User entered 'SYNTHROID'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'HYPOTHROIDISM'	Stacey Saldua (b) (4)	15 Oct 2020 20:03:48
	(b) (4)	

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '50'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User closed query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:44:32
Query 'Per CDM: ug is an option for dose units please reconcile.' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 17:54:03
User entered 'ug (ug)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 17:53:50
User opened query 'Per CDM: ug is an option for dose units please reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:51:51
User entered 'Other (OTHER)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 17:53:50
User entered 'MCG'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'once daily (QD)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

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US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4)	15 Oct 2020 20:03:48
	(b) (4)	

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'UN UNK 2013'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '0'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:03:48

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 20:03:48

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 05:18:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 05:18:07
Data point term sent to Coder	System	11 Nov 2020 17:28:59
User entered 'l-Lysine' reason for change: New Information	Avia McClain-Stocker (b) (4)	11 Nov 2020 17:28:54
Data point term sent to Coder	System	11 Nov 2020 16:45:30
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'Herpes' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
Data point term sent to Coder	System	11 Nov 2020 16:31:16
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
Data point term sent to Coder	System	11 Nov 2020 16:16:55
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:00:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:00:25
Data point term sent to Coder	System	15 Oct 2020 20:06:37
User entered 'L-LYSEINE'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'No (N)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Per CDM, re-query: Kindly review and clarify which data is entered in error and update to remove the log line which is not needed. Else, ensure the indication for this medication is recorded on the MH or AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 04:11:27
Query 'Per CDM, re-query: Kindly review and clarify which data is entered in error and update to remove the log line which is not needed. Else, ensure the indication for this medication is recorded on the MH or AE as appropriate.' answered with 'recorded in MH. please review' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:26:58
User opened query 'Per CDM, re-query: Kindly review and clarify which data is entered in error and update to remove the log line which is not needed. Else, ensure the indication for this medication is recorded on the MH or AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:34:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:34:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:45:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:45:01
User entered 'Herpes' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:01
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Data Entry Error Please remove line.' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:15:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:00:27
User entered 'HERPES'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered '1000' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'UNKNOWN'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'mg (mg)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Other (OTHER)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:06:42
User entered 'NOT LISTED' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:42
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:06:10
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'as needed (PRN)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'as needed (PRN)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 16:45:01
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:45:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 16:44:34
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Nov 2020 16:44:34
User entered 'un ' (non-conformant).	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'UN UNK 2003'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
User entered '1' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered '0'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'Yes (Y)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:01:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered empty.	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 16:44:34
User entered 'No (N)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:44:34
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:16:19
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
User entered empty; reason for change New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:17
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User entered empty.	System	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User entered empty.	System	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:31:07
DataPoint inactivated with code reason code Data not required.	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 16:16:36
User entered empty.	System	15 Oct 2020 20:06:10

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
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) (b) (4)	25 Feb 2021 14:11:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:11:53
Data point term sent to Coder	System	25 Feb 2021 14:10:44
User entered 'flonase'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 18:58:02
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:33:18
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:22:24
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'seasonal allergies'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

FDA-CBER-2022-1614-0217623

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:12:14
User entered '100'		25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered 'ug (ug)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:09:53

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '5 Aug 2020'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 14:09:53

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:13:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:13:53
Data point term sent to Coder	System	25 Feb 2021 14:12:51
User entered 'glimepiride'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'diabetes'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '4'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 14:11:52

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:18:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 14:18:53
Data point term sent to Coder	System	25 Feb 2021 14:17:55
User entered 'methocarbamol'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'muscle spasms'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1500'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 14:17:06

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:37:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:37:31
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Data point term sent to Coder	System	25 Feb 2021 14:18:55
User entered 'piaglitazon'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

FDA-CBER-2022-1614-0217675

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'diabetes'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '15'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'UN UNK 2008'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 14:18:30

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:17:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:17:42
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
Data point term sent to Coder	System	25 Feb 2021 14:31:18
User entered 'nitroglycerin'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		24 Mar 2021 12:48:28
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated tick mark' (Site from DM).	amy sheets (b) (4) (b) (4)	23 Mar 2021 16:21:12
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:22:44
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered 'chest pain nos'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
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).		02 Apr 2021 17:38:44
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	01 Apr 2021 13:24:24
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).	(b) (4), (b) (6)	29 Mar 2021 16:31:03
Signature has been broken.		29 Mar 2021 16:30:04
User entered '2.5' reason for change: Data Entry Error		29 Mar 2021 16:30:04
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 Mar 2021 07:22:50
User signature succeeded.	Judith Borger (b) (4) (b) (4)	25 Feb 2021 21:21:28
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:24:24
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 16:30:04
User entered 'mg (mg)' reason for change: Data Entry Error		29 Mar 2021 16:30:04
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
	(b) (4)	
User entered '5 Aug 2020'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User signature succeeded.	Judith Borger (b) (4)	25 Feb 2021 21:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User entered empty.	System	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User entered empty.	System	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:24
User entered empty.	System	25 Feb 2021 14:30:55

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:03:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:03:19
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
Data point term sent to Coder	System	03 May 2021 16:37:08
User entered 'ALBUTEROL'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'SHORTNESS OF BREATH/WHEEZING'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'MCG'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'four times daily (QID)'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
User entered '06 Apr 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 May 2021 16:38:51
User entered '27 Apr 2021'		03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 16:36:11

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFPODOXIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:39:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:39:26
Data point term sent to Coder	System	03 May 2021 16:39:09
User entered 'CEFPODOXIME'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
User entered 'KIDNEY INFECTION'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
	(b) (4)	
User entered '200'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered '06 Apr 2021'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 17:06:43
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 16:38:42

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 16:38:42

US3052028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 16:38:42

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:01:43

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:37
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
Signature has been broken.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:54:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 19:54:34
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	28 Oct 2020 18:09:57

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered '10 Mar 2021'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:00:54

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:43

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered 'Cholecystectomy' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:08:26
User entered 'CHOLECYCTECTOMY' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:07:21
User entered 'COLOECYCTECTOMY'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:00:54

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered 'Medical History (MH)'	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:00:54

US3052028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:01:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered empty.	Jeanette Mangual-Coughlin (b) (4) (b) (4)	06 Apr 2021 20:00:54

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

FDA-CBER-2022-1614-0217754

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '06/Aug/2020 11:04'	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
User entered '1'		06 Aug 2020 15:04:24

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'		06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

FDA-CBER-2022-1614-0217795

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '08/Oct/2020 11:19'	System	08 Oct 2020 15:19:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	Ernest Pheirim (b) (4) (b) (4)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '1'		08 Oct 2020 15:19:22

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

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Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

FDA-CBER-2022-1614-0217811

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

FDA-CBER-2022-1614-0217816

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

FDA-CBER-2022-1614-0217817

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '11/Nov/2020 16:35'	System	11 Nov 2020 21:35:46

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:44:14
User entered '1'		11 Nov 2020 21:35:46

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

FDA-CBER-2022-1614-0217831

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '12/Nov/2020 07:44'	System	12 Nov 2020 12:44:23

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 15:01:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:28:33
User entered '1'		12 Nov 2020 12:44:23

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '20/Nov/2020 15:28'	System	20 Nov 2020 20:28:45

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered '1'		20 Nov 2020 20:28:45

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

FDA-CBER-2022-1614-0217859

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '01/Dec/2020 16:07'	System	01 Dec 2020 16:07:35

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.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 16:07:35

FDA-CBER-2022-1614-0217875

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

FDA-CBER-2022-1614-0217889

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form (7)
Generated On: 09 Jun 2021 15:01:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '22/Dec/2020 16:29'	System	22 Dec 2020 21:29:26

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:29:31
User entered '1'		22 Dec 2020 21:29:26

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'		06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'		06 Aug 2020 15:03:22

FDA-CBER-2022-1614-0217899

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

FDA-CBER-2022-1614-0217907

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

FDA-CBER-2022-1614-0217908

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:01:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
User entered '24/Mar/2021 15:01'	System	24 Mar 2021 19:01:59

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:23
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:01:59

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'USA-US117-2020-MRNA-1273-P301000001'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

FDA-CBER-2022-1614-0217914

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:07:27
User entered 'Yes (Y)'	System	30 Nov 2020 14:08:55
Un-reviewed for Safety.	System	30 Nov 2020 13:32:38
DataPoint Un-verified.	System	30 Nov 2020 13:32:38
User entered 'No (N)'	System	30 Nov 2020 13:32:38
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Yes (Y)'	System	10 Nov 2020 18:39:28
Un-reviewed for Safety.	System	10 Nov 2020 17:28:57
User entered 'No (N)'	System	10 Nov 2020 17:28:57
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'Yes (Y)'	System	06 Aug 2020 15:03:22

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4)	11 Nov 2020 15:47:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Aug 2020 15:03:51
User entered 'No (N)'	System	06 Aug 2020 15:03:22

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Yaa'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Judith'	System	14 Sep 2020 21:41:19
Query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:46:53
User opened query 'Per ETRTR: Please complete data entry in all empty fields, thanks.' (Site from CRA).		07 Aug 2020 17:29:08

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
DataPoint Un-verified.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Oppong'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: User entered 'Borger'	System	14 Sep 2020 21:41:19

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '1565 Purdue Drive'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '1565 Purdue Drive'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'Fayetteville'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'Fayetteville'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered 'NC'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered 'NC' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered 'NC'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	26 Mar 2021 20:19:23
Un-reviewed for Safety.	System	24 Mar 2021 19:01:59
Signature has been broken.	System	24 Mar 2021 19:01:59
User entered '28314'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4) (b) (4)	23 Feb 2021 07:49:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 12:44:14
Un-reviewed for Safety.	System	11 Nov 2020 21:35:46
DataPoint Un-verified.	System	11 Nov 2020 21:35:46
User entered empty.	System	11 Nov 2020 21:35:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:35:32
DataPoint Verified.		11 Nov 2020 15:47:52
User entered '23303' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	11 Nov 2020 15:25:10
User entered empty.	System	10 Nov 2020 17:28:57
User entered '28303'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 21:41:04

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:47:52
Reviewed for Safety.		08 Oct 2020 15:19:13
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:03:20
User entered 'US' (non-conformant).	System	06 Aug 2020 15:04:24

US3052028

Folder: SAE USA-US117-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '8'	System	24 Mar 2021 19:01:59
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:49:23
	(b) (4)	
User entered '7'	System	22 Dec 2020 21:29:26
User entered '6'	System	01 Dec 2020 16:07:35
User entered '5'	System	20 Nov 2020 20:28:45
User entered '4'	System	12 Nov 2020 12:44:23
User entered '3'	System	11 Nov 2020 21:35:46
User entered '2'	System	08 Oct 2020 15:19:22
User entered '1'	System	06 Aug 2020 15:04:24

US3052028
Folder: SAE USA-US117-2020-MRNA-1273-P301000001
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 15:01:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered empty; reason for change Data Entry Error	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:56:06
User entered '03/Apr/2021 :' (non-conformant).	Jeanette Mangual-Coughlin (b) (4) (b) (4)	03 Apr 2021 13:53:06

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217937

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217941

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '' USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217950

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered '05/Apr/2021 06:13'	System	05 Apr 2021 13:13:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered '1'		05 Apr 2021 13:13:15

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217971

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217973

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered '07/Apr/2021 08:22'	System	07 Apr 2021 12:22:45

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:21:43
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	07 Apr 2021 15:18:54
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 12:22:45

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0217989

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 15:01:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	15 Apr 2021 16:22:25
User entered '15/Apr/2021 10:43'	System	15 Apr 2021 14:43:58

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:21:43
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:22:25
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:43:58

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218004

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218005

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218007

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218008

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218009

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	16 Apr 2021 15:23:57
User entered '16/Apr/2021 09:21'	System	16 Apr 2021 13:22:00

FDA-CBER-2022-1614-0218015

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)	28 Apr 2021 14:41:14
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:23:57
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 13:22:00

FDA-CBER-2022-1614-0218016

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

FDA-CBER-2022-1614-0218029

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

FDA-CBER-2022-1614-0218032

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 15:01:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	29 Apr 2021 13:58:33
User entered '28/Apr/2021 09:41'	System	28 Apr 2021 14:41:36

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 11:58:09
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	29 Apr 2021 13:58:33
User entered '1'	(b) (4), (b) (6)	28 Apr 2021 14:41:36

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'USA-US117-2021-MRNA-1273-P301000006'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yes (Y)'	System	05 Apr 2021 13:12:52

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'No (N)'	System	05 Apr 2021 13:12:52

Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Yaa'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Oppong'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '1565 Purdue Drive'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'Fayetteville'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered 'NC'	System	05 Apr 2021 13:12:52

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:13:07
User entered '28314'	System	05 Apr 2021 13:12:52

US3052028
Folder: SAE USA-US117-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:01:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:22:29
User entered 'US'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 11:58:34
User entered '5'	System	28 Apr 2021 14:41:36
User entered '4'	System	16 Apr 2021 13:22:00
User entered '3'	System	15 Apr 2021 14:43:58
User entered '2'	System	07 Apr 2021 12:22:45
User entered '1'	System	05 Apr 2021 13:13:15

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	03 May 2021 12:21:12
User entered '03/May/2021 07:58'	System	03 May 2021 11:58:34

US3052028

Folder: SAE USA-US117-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 12:21:12
User entered '1'	(b) (4) (b) (4), (b) (6)	03 May 2021 11:58:34