US3442087 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:42:24

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US3442087

Form: Participant Creation

Data signed: (b) (4) **23 Feb 2021 18:56:37**

Generated On: 09 Jun 2021 17:42:24

Participant ID	US3442087

mRNA-1273-P301 Completion Guidelines

US3442087

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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	SCRN

US3442087

Folder: Screening

Form: Demographics

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female ●
	Male ○
Ethnicity	Hispanic or Latino ○
	Not Hispanic or Latino ●
	Not Reported ○
	Unknown ○

Race (Check All That Apply)

White	False
Black	True
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 18:56:39**

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Date of Informed Consent *(dd MMM yyyy)*	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version
- Amendment 1 ◯
- Amendment 2 ◯
- Amendment 3 ⬤
- Amendment 4 ◯
- Amendment 5 ◯

Was participant enrolled in the study?
- Yes ⬤
- No ◯

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?
- Yes ◯
- No ⬤

If Yes, previous participant number _____

Enrollment Trigger	1

US3442087

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **23 Feb 2021 18:56:39**

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Did the participant meet all eligibility criteria?　　　　　　　　　　　　Yes ●

No ◯

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **23 Feb 2021 18:56:39**

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Were any significant conditions reported?   Yes ●

                                             No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 18:56:39

Generated On: 09 Jun 2021 17:42:24

Condition	PCN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:56:39

Generated On: 09 Jun 2021 17:42:24

Condition	MORPHINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	AMLODIPINE ALLERGY
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	TOMATO ALLERGY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	PEANUT BUTTER ALLERGY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 18:56:39

Generated On: 09 Jun 2021 17:42:24

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	HYPERTHYROIDISM
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) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	MILD DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	PANIC ATTACKS
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	CYST IN THYROID BENIGN
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	MYOMECTOMY
Start date (dd MMM yyyy)	UN FEB 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2018
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	FEB 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Condition	THYROID REMOVAL
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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

US3442087
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **23 Feb 2021 18:56:39**
Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	15:58 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:58
Height *(xxx.x)*	72.0 in
Weight *(xxx.x)*	240.0 lb
BMI *(xxx.x)*	32.61791 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)	

US3442087

Folder: Screening

Form: Physical Examination

Data signed: [(b) (4)] **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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.

Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Is the participant of childbearing potential?	Yes ●
	No ○
If No, what is the reason?	Surgically sterile ○
	Post-menopausal ○
	Partner medically sterile ○
	Not reached age of Menarche ○
	Other ○
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) **23 Feb 2021 18:56:39**

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Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	25 AUG 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **23 Feb 2021 18:56:39**

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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	SUPPLY CHAIN ORDER MANAGEMENT

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 18:56:39**

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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 18:56:40**

Generated On: 09 Jun 2021 17:42:24

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **23 Feb 2021 18:56:40**

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What was the date of randomization? *(dd MMM yyyy)*	25 AUG 2020
What was the participant's randomization number?	108474

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○ No ●
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○ No ●
Severe obesity (body mass index > or = 40kg/m2)	Yes ○ No ●
Diabetes (Type I, Type 2, or gestational)	Yes ○ No ●
Liver Disease	Yes ○ No ●
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **23 Feb 2021 18:56:40**

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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 18:56:40**

Generated On: 09 Jun 2021 17:42:24

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)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	15:58 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:58
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 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 18:56:40**

Generated On: 09 Jun 2021 17:42:24

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)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	18:15 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 18:15
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 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 18:56:40**

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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: Pregnancy Test

Data signed: (b) (4) **23 Feb 2021 18:56:40**

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Was the pregnancy test performed?   Yes ◯

No ⬤

Date of test *(dd MMM yyyy)* _____

Test performed   Urine ◯

Serum ◯

Result   Positive ◯

Negative ◯

Was FSH sample collected?   Yes ◯

No ⬤

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) **23 Feb 2021 18:56:40**

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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)*	17:35 (24 HR)
Treatment Date and Time (derived)	25 AUG 2020 17:35
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

US3442087

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	25 AUG 2020
Collection time *(00:00-23:59)*	14:40 (24 HR)
Collection date and time (derived)	25 AUG 2020 14:40

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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	14:45	25 AUG 2020 14:45
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2401163

US3442087

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                 No ◯

Continuing Flag   1

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	25 AUG 2020 18:13
PC Open Date & Time	25 AUG 2020 17:55
PC Close Date & Time	25 AUG 2020 20:25

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes	●
	No	○
Please record your **TEMPERATURE in °F**		98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes	○
	No	●

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

PC Time Stamp	25 AUG 2020 21:42
PC Open Date & Time	25 AUG 2020 21:20
PC Close Date & Time	26 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24

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**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.7 °F

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

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

PC Time Stamp	27 AUG 2020 12:53
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:24

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	28 AUG 2020 12:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 AUG 2020 16:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:24

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

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

FDA-CBER-2022-1614-2401171

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °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	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-2401172

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

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	25 AUG 2020 18:14
PC Open Date & Time	25 AUG 2020 17:55
PC Close Date & Time	25 AUG 2020 20:25

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:24

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	25 AUG 2020 21:43
PC Open Date & Time	25 AUG 2020 21:20
PC Close Date & Time	26 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

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 12:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:24

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	27 AUG 2020 12:54
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:24

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	28 AUG 2020 12:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-2401177

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:24

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	29 AUG 2020 16:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:24

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 12:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

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

PC Time stamp	25 AUG 2020 18:14
PC Open Date & Time	25 AUG 2020 17:55
PC Close Date & Time	25 AUG 2020 20:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24

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 ○

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

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

PC Time stamp	25 AUG 2020 21:44
PC Open Date & Time	25 AUG 2020 21:20
PC Close Date & Time	26 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24

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	26 AUG 2020 12:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24

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 ◯

PC Time stamp	27 AUG 2020 12:55
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24

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	28 AUG 2020 12:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24

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 ●

FDA-CBER-2022-1614-2401191

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24

	Yes ◯
PC Time stamp	29 AUG 2020 16:21
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24

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 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:24

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 12:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:42:24

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	02 SEP 2020 06:58
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	02 SEP 2020 06:58
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯

PC Time stamp	02 SEP 2020 12:16
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 17:42:24

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	02 SEP 2020 06:59
PC Open Date and Time	01 SEP 2020 12:00
PC Close Date and Time	02 SEP 2020 11:59

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 9
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 SEP 2020 12:16
PC Open Date and Time	02 SEP 2020 12:00
PC Close Date and Time	03 SEP 2020 11:59

US3442087

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3442087

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3442087

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

          No ◯

Continuing Flag   1

US3442087

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was this visit performed?	Yes ●
	No ◯
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●
Folder OID	VISIT2

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	28 SEP 2020
Time of assessment *(00:00-23:59)*	08:39 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:39
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Timepoint   Pre-Dose ○

                                                                    Post-Dose ●

Were vital signs assessed?   Yes ○

                                                                         No ●

Date of assessment *(dd MMM yyyy)* _____

Time of assessment *(00:00-23:59)* _____

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

  Route of measurement   Oral ○

                                                                    Axillary ○

                                                                       Other ○

  If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

FDA-CBER-2022-1614-2401210

US3442087

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   28 SEP 2020

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

US3442087

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?	Yes ⬤
	No ◯
Date of test *(dd MMM yyyy)*	28 SEP 2020
Test performed	Urine ⬤
	Serum ◯
Result	Positive ◯
	Negative ⬤
Was FSH sample collected?	Yes ◯
	No ⬤
Collection date	
Collection time	
Collection date and time (derived)	

US3442087
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **13 Apr 2021 15:20:35**
Generated On: 09 Jun 2021 17:42:24

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   SUBJECT DID NOT WITHDRAW
Participant, Protocol Deviation, or Other, specify   CONSENT, BUT WISHED TO
                                                                 WITHDRAW FROM RECEIVING
                                                                 SECOND DOSING.

What was the study treatment?   _____

What was the treatment date? *(dd MMM yyyy)*   _____

What was the treatment time? *(00:00-23:59)*   _____

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯

                                                            Right Arm ◯

What was the frequency of the study treatment dosing?   _____

What was the route of administration for the study treatment?   _____

FDA-CBER-2022-1614-2401213

US3442087

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	28 SEP 2020
Collection time *(00:00-23:59)*	08:50 (24 HR)
Collection date and time (derived)	28 SEP 2020 08:50

US3442087

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*			28 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:55	28 SEP 2020 08:55
Nasopharyngeal Swab 2	No		

US3442087
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **13 Apr 2021 15:20:35**
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3442087

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3442087

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3442087

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3442087

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

Time of assessment *(00:00-23:59)* _____

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

FDA-CBER-2022-1614-2401224

US3442087

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

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.

US3442087

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 18:56:40**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	23 OCT 2020
Collection time *(00:00-23:59)*	08:11 (24 HR)
Collection date and time (derived)	23 OCT 2020 08:11

US3442087
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 18:56:40**
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ◯

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ⬭

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:21:14
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:16:58
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 16:55:59
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 15:24:15
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 07:25:43
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 00:02:40
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 20:04:47
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 14:50:00
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have 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	28 JAN 2021 06:35:50
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 17:00:33
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 06:53:38
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 17:07:58
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 07:08:47
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 06:08:10
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯
Have 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 ◯
Date and time of submission	11 MAR 2021 07:03:57
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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	18 MAR 2021 07:43:44
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 05:48:07
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 06:43:18
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⚪
Have 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	08 APR 2021 07:53:31
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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	15 APR 2021 06:51:30
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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	24 APR 2021 12:58:40
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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	02 MAY 2021 16:22:35
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   **DAY 257**

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-2401262

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   DAY 271

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-2401264

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 278

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⃝

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⭕

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   **DAY 299**

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

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

Fever (Temperature ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	**DAY 306**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⭕

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

FDA-CBER-2022-1614-2401288

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   DAY 362

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

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

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

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT **DAY 411**

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 $\geq$ 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-2022-1614-2401306

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 $\geq$ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   DAY 432

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

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

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

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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-2022-1614-2401312

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⭘

FDA-CBER-2022-1614-2401316

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

FDA-CBER-2022-1614-2401320

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

FDA-CBER-2022-1614-2401322

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 481

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-2401324

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   **DAY 488**

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

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

Fever (Temperature ≥ 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-2022-1614-2401326

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

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

Fever (Temperature ≥ 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 ⃝

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	**DAY 502**

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

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

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

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

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

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

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

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 509

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

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⬭

FDA-CBER-2022-1614-2401334

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 537

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

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

Fever (Temperature ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	**DAY 544**

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

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

Fever (Temperature ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 551

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

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

Fever (Temperature ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 558

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-2401346

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   **DAY 565**

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

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

FDA-CBER-2022-1614-2401348

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⃝

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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-2022-1614-2401356

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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-2022-1614-2401360

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⃝

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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-2022-1614-2401366

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 642

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

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

Fever (Temperature ≥ 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 ⭕

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ⭕

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   **DAY 656**

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

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

Fever (Temperature ≥ 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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT   DAY 663

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

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

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

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 677

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-2401380

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

FDA-CBER-2022-1614-2401382

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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 ⬭ |

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

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 ⚪

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ⬭

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ⚪

FDA-CBER-2022-1614-2401392

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 726

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

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

Fever (Temperature ≥ 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-2022-1614-2401394

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ⬭

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT	**DAY 754**

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

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

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

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

FDA-CBER-2022-1614-2401402

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT DAY 775

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

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

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

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

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

FDA-CBER-2022-1614-2401410

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 ≥ 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-2022-1614-2401412

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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):

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 ◯

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

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		05 MAR 2021 06:07:49

US3442087
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 18:56:39**
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 NOV 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                          No ⭕

Continuing Flag   1

US3442087

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3442087

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3442087

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 18:56:39**
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3442087

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	19 MAR 2021

Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4)   **28 Apr 2021 07:46:05**
Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

Time of assessment *(00:00-23:59)* _____

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement
- Oral ◯
- Axillary ◯
- Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442087

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?   Yes ●

                                                                            No ○

Date of examination *(dd MMM yyyy)*   19 MAR 2021

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

US3442087

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	08:37 (24 HR)
Collection date and time (derived)	19 MAR 2021 08:37

US3442087

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                                                                          No ○

Continuing Flag   1

US3442087

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **28 Apr 2021 07:46:05**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3442087

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **28 Apr 2021 07:46:05**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ⭕

Continuing Flag   1

US3442087
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

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

US3442087
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:42:24

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 ⬭

US3442087

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:42:24

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3442087

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

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	25 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3442087

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

Form: Unblinding

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Date of updated informed consent *(dd MMM yyyy)*	25 JAN 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)*	21 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	1

US3442087

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Height	
Weight	
BMI (xxx.x)	

US3442087

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬤
	Post-Dose ⭕
Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	25 JAN 2021
Time of assessment *(00:00-23:59)*	14:13 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 14:13
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3442087

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ○
	Post-Dose ●
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	25 JAN 2021
Time of assessment *(00:00-23:59)*	15:58 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 15:58
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

US3442087

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

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?   Yes ●

                                                                 No ◯

Date of examination *(dd MMM yyyy)*   25 JAN 2021

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

US3442087

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

Form: Pregnancy Test

Data signed: (b) (4) **18 Mar 2021 21:35:59**

Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?	Yes ⬤
	No ◯
Date of test *(dd MMM yyyy)*	25 JAN 2021
Test performed	Urine ⬤
	Serum ◯
Result	Positive ◯
	Negative ⬤
Was FSH sample collected?	Yes ◯
	No ⬤
Collection date	
Collection time	
Collection date and time (derived)	

Was study treatment given?	Yes ●
	No ○

If No, reason not given	
	Participant declined due to Adverse Event ○
	Physician withheld dose due to Adverse Event ○
	Death ○
	Lost To Follow-Up ○
	Physician Decision ○
	Pregnancy ○
	Protocol Deviation ○
	Study Terminated by Sponsor ○
	Withdrawal of Consent by Participant ○
	Confirmed COVID-19 ○
	Other ○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	25 JAN 2021
What was the treatment time? *(00:00-23:59)*	15:26 (24 HR)
Treatment Date and Time (derived)	25 JAN 2021 15:26
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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Apr 2021 15:20:35**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	25 JAN 2021
Collection time *(00:00-23:59)*	14:26 (24 HR)
Collection date and time (derived)	25 JAN 2021 14:26

US3442087

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **18 Mar 2021 21:35:59**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	25 JAN 2021
Collection time *(00:00 - 23:59)*	14:24
Collection Date and Time (derived)	25 JAN 2021 14:24

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

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?   Yes ●

                                                                    No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   1 FEB 2021

Please select one status for the follow-up contact   Contact Made ●

                                                      Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 18:56:39**

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?   Yes ●

                                                      No ○

Continuing Flag	1
OLD29 Placebo Flag	1

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Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

| Was this visit performed? | Yes ⬤ |
| | No ◯ |

| Visit date (dd MMM yyyy) | 22 FEB 2021 |

| Was visit performed at the participant's home or at the clinic? | Home ◯ |
| | Clinic ⬤ |

| Folder OID | OLD29 |

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Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	22 FEB 2021
Time of assessment *(00:00-23:59)*	17:15 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 17:15
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442087

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:56:38

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?
Yes ●
No ○

Date of examination *(dd MMM yyyy)*
22 FEB 2021

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

US3442087

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?	Yes ●
	No ◯
Collection date *(dd MMM yyyy)*	22 FEB 2021
Collection time *(00:00-23:59)*	17:17 (24 HR)
Collection date and time (derived)	22 FEB 2021 17:17

US3442087

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Did the participant experience any adverse events?   Yes ●

                                                           No ◯

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	GENERAL JOINT ACHES
Was this a medically-attended AE?	Yes ◯
	No ⬤
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	31 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ◯
If not Ongoing, end date *(dd MMM yyyy)*	23 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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	
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)	

AEID _____

Adverse event | INTERMITTENT LOW BACK 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)* | 22 SEP 2020

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

AE start date and time (derived) | _____

Ongoing? | Yes ◯ No ⬤

If not Ongoing, end date *(dd MMM yyyy)* | 23 OCT 2020

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

AE End Date and Time (derived) | _____

Severity | Grade 1/Mild ⬤ Grade 2/Moderate ◯ Grade 3/Severe ◯ Grade 4 ◯

Is the adverse event serious? | Yes ◯ No ⬤

AE is serious due To (check all that apply)

Death | False

Life threatening | False

Requires inpatient or prolongation of existing Hospitalization | False

Hospital Admission Date *(dd MMM yyyy)* | _____

Hospital Discharge Date *(dd MMM yyyy)* | _____

Admitted to ICU? | Yes ◯ No ◯ Unknown ◯

Number of Days in ICU | _____

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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	
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 (3)

Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	SINUS INFECTION
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)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ◯
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	SINUS INFECTION
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	30 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ○
If not Ongoing, end date *(dd MMM yyyy)*	08 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	
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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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

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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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	INFECTED LEFT FOREARM TATTOO
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)	6 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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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 _____

Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

AEID	
Adverse event	UNDERARM GLAND SWELLING
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)	02 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ⚪
	No ⬤
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ⚪
	Grade 3/Severe ⚪
	Grade 4 ⚪
Is the adverse event serious?	Yes ⚪
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ⚪
	No ⚪
	Unknown ⚪
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24

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 (8)

Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	UPPER RESPIRATORY INFECTION
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 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)*	15 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	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events
Form: Adverse Events (9)
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AEID	
Adverse event	NAUSEA INTERMITTENT
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)	5 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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 _____

Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

FDA-CBER-2022-1614-2401471

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24

AEID	
Adverse event	THYROID CANCER
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)	22 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)	
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)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	23 APR 2021
Admitted to ICU?	Yes ○
	No ●
	Unknown ○
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	False
Concomitant Procedure	True

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 INFORMED SITE OF HAVING A THYROIDECTOMY DISCOVERING THYROID CANCER. MEDICAL RECORDS HAVE BEEN REQUESTED.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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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.

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	POTASSIUM

Prophylaxis

Yes ⬤(No)
No ⬤

Indication	LOW POTASSIUM
Dose per administration	20

Dose unit

mg ⬤
ug ○
mL ○
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

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)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ●
Separate Dosage Number (derived)	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) **28 Apr 2021 07:46:04**

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Name of Medication	ALLERGRA
Prophylaxis	Yes ⚪
	No ⚫
Indication	ALLERGIES
Dose per administration	1
Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚫
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚫
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
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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 FEB 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	TINTELLIX

Prophylaxis	Yes ◯
	No ⬤

Indication	ANXIETY
Dose per administration	5

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

	Intramuscular ◯
	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 2019

Start date completely unknown — False

Ongoing? — Yes ● No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event? — Yes ◯ No ●

Separate Dosage Number (derived) — 1

Interval Dosage Unit Number (derived) — 1

Interval Dosage Definition (derived) — 802 ◯ 803 ◯ 804 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	EDARBI
Prophylaxis	Yes ⚪
	No ⬤
Indication	HYPERTENSION
Dose per administration	40
Dose unit	mg ⬤
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	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 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	SINGULAIR

Prophylaxis	Yes ◯
	No ⬤

Indication	ALLERGIES

Dose per administration	10

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	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 (6)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	OZEMPIC
Prophylaxis	Yes ⚪
	No ⚫
Indication	PCOS
Dose per administration	.75
Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚫
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚫
	Transdermal ⚪
	Intraocular ⚪

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 2019
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ⬤
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	CHLORATHALIDONE

Prophylaxis	
	Yes ◯
	No ⬤

Indication	HYPERTENSION
Dose per administration	25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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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 JAN 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ⬤
	No ◯
Indication	INFLUENZA
Dose per administration	0.5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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)*	12 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 2020
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) **28 Apr 2021 07:46:04**

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Name of Medication	IBUPROFEN

Prophylaxis		
	Yes	○
	No	●

Indication	JOINT ACHES
Dose per administration	400

Dose unit		
	mg	●
	ug	○
	mL	○
	g	○
	IU	○
	tablet	○
	capsule	○
	puff	○
	Other	○

If dose unit is Other, specify _____

Frequency		
	once daily	○
	twice daily	○
	three times daily	○
	four times daily	○
	every other day	○
	every week	○
	every month	○
	as needed	●
	once	○
	unknown	○
	other	○

If frequency is Other, specify _____

Route of administration		
	Oral	●
	Topical	○
	Subcutaneous	○
	Transdermal	○
	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)*	31 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	23 OCT 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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	ROBAXIN
Prophylaxis	Yes ○
	No ●
Indication	INTERMITTENT LOWER BACK PAIN
Dose per administration	500
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

	Intraocular ◯
	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)*	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	23 OCT 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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

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Name of Medication	DOXYCYCLINE
Prophylaxis	Yes ◯
	No ⬤
Indication	SINUS INFECTION
Dose per administration	100
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ⬤
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

	Intramuscular	◯
	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)*	19 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	26 OCT 2020
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 ⬤

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	TRINTELLIX
Prophylaxis	Yes ◯
	No ⬤

Indication	ANXIETY
Dose per administration	20
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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)*	20 NOV 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	CEFDINIR
Prophylaxis	Yes ◯
	No ⬤
Indication	SINUS INFECTION
Dose per administration	300
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)

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

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)*	30 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	08 JAN 2021
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 (14)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	MIRTAZAPINE
Prophylaxis	Yes ⚪
	No ⚫
Indication	ANXIETY AND SLEEP AID
Dose per administration	22

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	EVERY NIGHT

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **28 Apr 2021 07:46:04**
Generated On: 09 Jun 2021 17:42:24

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4)   28 Apr 2021 07:46:04

Generated On: 09 Jun 2021 17:42:24

Name of Medication	TRULICITY
Prophylaxis	Yes ⭘
	No ⬤
Indication	POLYCYSTIC OVARY SYNDROME (PCOS)
Dose per administration	.75
Dose unit	mg ⬤
	ug ⭘
	mL ⭘
	g ⭘
	IU ⭘
	tablet ⭘
	capsule ⭘
	puff ⭘
	Other ⭘
If dose unit is Other, specify	
Frequency	once daily ⭘
	twice daily ⭘
	three times daily ⭘
	four times daily ⭘
	every other day ⭘
	every week ⭘
	every month ⭘
	as needed ⭘
	once ⭘
	unknown ⭘
	other ⬤
If frequency is Other, specify	EVERY OTHER WEEK
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 DEC 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	HYDROCORTISONE CREAM
Prophylaxis	Yes ◯
	No ⬤
Indication	LEFT ARM INFECTION
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	APPLICATION
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ⬤
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

	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)*	16 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	18 APR 2021
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 (17)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	TRIPLE ANTIBIOTIC OINTMENT (NEOMYCIN, BACITRACIN, POLYMYXIN)

Prophylaxis
- Yes ○
- No ●

Indication	LEFT ARM INFECTION
Dose per administration	1

Dose unit
- mg ○
- ug ○
- mL ○
- g ○
- IU ○
- tablet ○
- capsule ○
- puff ○
- Other ●

If dose unit is Other, specify	APPLICATION

Frequency
- once daily ○
- twice daily ○
- three times daily ○
- four times daily ○
- every other day ○
- every week ○
- every month ○
- as needed ●
- once ○
- unknown ○
- other ○

If frequency is Other, specify

Route of administration
- Oral ○
- Topical ●
- Subcutaneous ○
- Transdermal ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

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)*	16 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 APR 2021
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 ◯

Name of Medication	CEFTIN
Prophylaxis	Yes ◯
	No ⬤
Indication	UPPER RESPIRATORY INFECTION
Dose per administration	500
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ⬤
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 APR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 APR 2021
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 ⬤

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	ALBUTEROL INHALER

Prophylaxis	
	Yes ◯
	No ⬤

Indication	UPPER RESPIRATORY INFECTION

Dose per administration	2

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)*	05 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	ONDANSETRON

Prophylaxis

Yes ◯
No ⬤

Indication	NAUSEA INTERMITTENT
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)*	5 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

FDA-CBER-2022-1614-2401514

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **28 Apr 2021 07:46:04**

Generated On: 09 Jun 2021 17:42:24

Name of Medication	ELETONE CREAM

Prophylaxis
Yes ◯
No ⬤

Indication	INFECTION (L) FOREARM
Dose per administration	1

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

If dose unit is Other, specify	APPLICATION

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

If frequency is Other, specify _____

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

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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)*	06 APR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 APR 2021
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 ◯

US3442087

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Were any concomitant procedures performed? Yes ◯

No ⬤

If yes, please complete Concomitant Procedures form.

US3442087

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4)   **23 Feb 2021 18:56:38**

Generated On: 09 Jun 2021 17:42:24

Date of dosing discontinuation (dd MMM yyyy)	24 SEP 2020

Primary reason for dosing discontinuation	
AE (specify)	◯
SAE (specify)	◯
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	⬤
Due to SARS-COV-2	◯
Other	◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT DID NOT LIKE SOLICITED REACTIONS CAUSED BY THE VACCINE AND "DOES NOT TRUST" THE 2ND DOSE.

US3442087
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:24

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 ◯

Audit

US3442087 (Prod: Benchmark Research - Fort Worth)

US3442087

Form: Participant Creation

Generated On: 09 Jun 2021 17:42:24

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'US3442087'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:39:46

US3442087
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:43:22

US3442087

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:39:47

US3442087
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:43:22

US3442087
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'SCRN'	System	25 Aug 2020 22:43:22

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:39:48

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '43'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'YEARS'	System	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '43'	System	25 Aug 2020 22:44:36

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Female (F)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

FDA-CBER-2022-1614-2401536

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:24
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:11

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

FDA-CBER-2022-1614-2401541

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Aug 2020'	System	25 Aug 2020 22:44:36

FDA-CBER-2022-1614-2401542

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2020'	System	25 Aug 2020 22:44:36

US3442087
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:24
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Amendment 3 (3)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

FDA-CBER-2022-1614-2401547

US3442087
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:24

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:36

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:39:47

US3442087

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:24

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1'	System	25 Aug 2020 22:44:40

US3442087
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:42:24
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:40

FDA-CBER-2022-1614-2401551

US3442087

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:42:24

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:31

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:56:56
Data point term sent to Coder	System	26 Aug 2020 14:55:25
User entered 'PCN ALLERGY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:02

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
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: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 11:14:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 11:14:51
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 Sep 2020 21:59:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:59:50
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)	26 Aug 2020 14:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:56:56
Data point term sent to Coder	System	26 Aug 2020 14:55:27
User entered 'MORPHINE ALLERGY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:24
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:26

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
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)	26 Aug 2020 14:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:57:48
Data point term sent to Coder	System	26 Aug 2020 14:56:30
User entered 'AMLODIPINE ALLERGY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Mar 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Mar 2020'	System	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2020'	System	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:52

US3442087

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:55:52

US3442087
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:00:43
Data point term sent to Coder	System	26 Aug 2020 14:59:41
User entered 'ALLERGIC RHINITIS'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 1995'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:24
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 1995'	System	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1995'	System	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 14:59:39

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:01:45
Data point term sent to Coder	System	26 Aug 2020 15:00:41
User entered 'TOMATO ALLERGY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2015'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

FDA-CBER-2022-1614-2401594

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2015'	System	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2015'	System	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:00:11

US3442087
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:00:11

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Peanut allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 00:00:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 00:00:34
Data point term sent to Coder	System	26 Aug 2020 15:01:42
User entered 'PEANUT BUTTER ALLERGY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2015'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

FDA-CBER-2022-1614-2401604

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

FDA-CBER-2022-1614-2401607

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2015'	System	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2015'	System	26 Aug 2020 15:01:01

FDA-CBER-2022-1614-2401610

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:01:01

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:03:41
Data point term sent to Coder	System	26 Aug 2020 15:02:45
User entered 'ANEMIA'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:02:03

US3442087
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:02:03

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:04:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:04:49
Data point term sent to Coder	System	26 Aug 2020 15:03:50
User entered 'GERD'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

FDA-CBER-2022-1614-2401626

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

FDA-CBER-2022-1614-2401627

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:15

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:03:15

US3442087

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:03:15

US3442087
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:03:15

US3442087
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:03:15

US3442087
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
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)	26 Aug 2020 15:04:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:04:47
Data point term sent to Coder	System	26 Aug 2020 15:03:50
User entered 'HEARTBURN'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

FDA-CBER-2022-1614-2401636

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:03:43

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 01:33:46
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 01:33:34
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:06:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:06:48
Data point term sent to Coder	System	26 Aug 2020 15:05:53
User entered 'HYPERTHYROIDISM'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

FDA-CBER-2022-1614-2401643

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2017'	System	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2017'	System	26 Aug 2020 15:05:19

US3442087

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2017'	System	26 Aug 2020 15:05:19

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2017'	System	26 Aug 2020 15:05:19

US3442087
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:31:28
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'correct as entered' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:00:34
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 01:34:35
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)	26 Aug 2020 15:06:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:06:48
Data point term sent to Coder	System	26 Aug 2020 15:05:53
User entered 'HYPOTHYROIDISM'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

FDA-CBER-2022-1614-2401654

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review the status of this condition as there is a procedure of "Thyroid Removal" that was entered in the medical history (2002). It is unexpected that the condition would be ongoing after the thyroid has been removed. Please confirm and update the stop date of this condition. Otherwise, please provide explanation.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:31:30
Query 'Per DM CLR: Please review the status of this condition as there is a procedure of "Thyroid Removal" that was entered in the medical history (2002). It is unexpected that the condition would be ongoing after the thyroid has been removed. Please confirm and update the stop date of this condition. Otherwise, please provide explanation.' answered with 'correct as entered' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:00:44
User opened query 'Per DM CLR: Please review the status of this condition as there is a procedure of "Thyroid Removal" that was entered in the medical history (2002). It is unexpected that the condition would be ongoing after the thyroid has been removed. Please confirm and update the stop date of this condition. Otherwise, please provide explanation.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 01:35:03
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:05:50

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US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:05:50

US3442087

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:05:50

US3442087
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:50
Data point term sent to Coder	System	26 Aug 2020 15:06:54
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2016'	System	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2016'	System	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:06:20

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:49
Data point term sent to Coder	System	26 Aug 2020 15:06:56
User entered 'MILD DEPRESSION'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

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US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:06:44

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:07:50
Data point term sent to Coder	System	26 Aug 2020 15:07:02
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

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US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:07:00

US3442087
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:00

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:52
Data point term sent to Coder	System	26 Aug 2020 15:08:06
User entered 'PANIC ATTACKS'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Mar 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

FDA-CBER-2022-1614-2401694

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Mar 2020'	System	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2020'	System	26 Aug 2020 15:07:29

US3442087
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:29

US3442087
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:29

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:51
Data point term sent to Coder	System	26 Aug 2020 15:08:06
User entered 'INSOMNIA'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2015'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

FDA-CBER-2022-1614-2401704

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2015'	System	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2015'	System	26 Aug 2020 15:07:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:47

US3442087
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:07:47

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:08:52
Data point term sent to Coder	System	26 Aug 2020 15:08:06
User entered 'MIGRAINES'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 1995'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 17:42:24
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 1995'	System	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1995'	System	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Aug 2020 15:08:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:09:41
Data point term sent to Coder	System	26 Aug 2020 15:09:10
User entered 'UTERINE FIBROIDS'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

FDA-CBER-2022-1614-2401724

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 15:09:26
User entered 'No (N)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:09:05
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

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US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2018' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:26
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2018'	System	26 Aug 2020 15:09:26
User entered empty.	System	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:09:26
User entered empty.	System	26 Aug 2020 15:09:05

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please update the condition to confirm if the THYROID CYST was benign or cancerous. 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)	13 Nov 2020 00:41:07
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid neoplasms, PT: Thyroid cyst, LLT: Thyroid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 07:12:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 07:12:22
Data point term sent to Coder	System	23 Oct 2020 14:39:00
Query 'Per DM CLR: Please update the condition to confirm if the THYROID CYST was benign or cancerous. 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 'confirmed benign cyst' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:38:55
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 14:38:43
User entered 'CYST IN THYROID benign' reason for change: Data Entry Error		23 Oct 2020 14:38:43
User opened query 'Per DM CLR: Please update the condition to confirm if the THYROID CYST was benign or cancerous. 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).		21 Oct 2020 15:51:41
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid neoplasms, PT: Thyroid cyst, LLT: Thyroid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:37:42

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US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:37:42
Data point term sent to Coder	System	26 Aug 2020 15:11:14
User entered 'CYST IN THYROID'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 15:11:04

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Myomectomy, LLT: Myomectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:13:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:13:48
Data point term sent to Coder	System	26 Aug 2020 15:12:15
User entered 'MYOMECTOMY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Feb 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Feb 2018'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

FDA-CBER-2022-1614-2401748

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Feb 2018'	System	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Feb 2018'	System	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2018'	System	26 Aug 2020 15:11:34

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:13:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:13:47
Data point term sent to Coder	System	26 Aug 2020 15:12:17
User entered 'THYROID REMOVAL'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2002'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 15:12:12

FDA-CBER-2022-1614-2401760

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2002'	System	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2002'	System	26 Aug 2020 15:12:12

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:08:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:08:25
Data point term sent to Coder	System	14 Oct 2020 22:07:48
User entered 'polycystic ovary syndrome'	(b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2019'	System	14 Oct 2020 22:07:01

US3442087
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:42:24
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2019'	System	14 Oct 2020 22:07:01

US3442087
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:42:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:07:01

US3442087
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:42:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:07:01

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Investigations, HLGT: Water, electrolyte and mineral investigations, HLT: Mineral and electrolyte analyses, PT: Blood potassium decreased, LLT: Potassium low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:11:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:11:16
Data point term sent to Coder	System	14 Oct 2020 22:09:53
User entered 'low potassium'	(b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'Jan 2019'	System	14 Oct 2020 22:08:58

US3442087
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 17:42:24
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '2019'	System	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:08:58

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '15:58'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Aug 2020 15:58'	System	26 Aug 2020 14:37:15

FDA-CBER-2022-1614-2401787

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '72.0' in	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15
DataPoint set to visible.	System	25 Aug 2020 22:44:40

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '240.0' lb	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15
DataPoint set to visible.	System	25 Aug 2020 22:44:40

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
Amendment Manager: User entered '32.61791'	System	17 Sep 2020 00:02:46
User entered '32.6'	System	26 Aug 2020 14:37:15
DataPoint set to visible.	System	25 Aug 2020 22:44:40

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'kg/m2'	System	26 Aug 2020 14:37:15
DataPoint set to visible.	System	25 Aug 2020 22:44:40

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'bpm'	System	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'breaths/min'	System	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Aug 2020 14:37:15

US3442087

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Aug 2020 14:37:15

US3442087
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31

US3442087

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:23

US3442087

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:37:23

US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 17:42:24
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

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US3442087

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:24

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:00

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

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US3442087
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Urine (URINE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 15:17:41
Query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:15:56
User opened query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:06:47
User entered 'Negative (NEGATIVE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:15:50
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:15:50
User entered '16:25'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	07 Oct 2020 17:15:50
User entered '25 Aug 2020 16:25'	System	26 Aug 2020 14:38:39

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

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US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:24
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:24
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'SUPPLY CHAIN ORDER MANAGEMENT'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

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)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

US3442087

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:24

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:39:56

FDA-CBER-2022-1614-2401843

US3442087
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:50

US3442087

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:50

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US3442087

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:44:50

US3442087
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'VISIT1'	System	25 Aug 2020 22:44:50

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 22:04:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '108474'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 22:04:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 22:04:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

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)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

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)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:15

US3442087
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:24
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:15

US3442087

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:13:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:56:13
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:56:11

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

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US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:24
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

FDA-CBER-2022-1614-2401860

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '15:58'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '25 Aug 2020 15:58'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '98.6' F	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '81'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'bpm'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '12'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'breaths/min'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '133'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'mmHg'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '89'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'mmHg'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

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US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '18:15'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '25 Aug 2020 18:15'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '97.3' F	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '67'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'bpm'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '14'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'breaths/min'	System	26 Aug 2020 15:14:29

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '140'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'mmHg'	System	26 Aug 2020 15:14:29

US3442087

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '89'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 15:14:29

US3442087
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:24
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'mmHg'	System	26 Aug 2020 15:14:29

US3442087
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:20

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:40:20

US3442087

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 19:48:55
User entered 'Yes (Y)' reason for change: Per Query Resolution		16 Oct 2020 20:59:43
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).		09 Oct 2020 15:17:25
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'DONE' (Site from DM).		07 Oct 2020 17:12:03
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	07 Oct 2020 17:11:58
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	07 Oct 2020 17:11:33
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Oct 2020 17:11:33
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).		07 Oct 2020 10:07:34
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:48:55
User entered '25 Aug 2020' reason for change: Data Entry Error		16 Oct 2020 20:59:43
User entered empty; reason for change Data Entry Error		07 Oct 2020 17:11:58
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:48:55
User entered 'Urine (URINE)' reason for change: Data Entry Error		16 Oct 2020 20:59:43
User entered empty; reason for change Data Entry Error		07 Oct 2020 17:11:58
User entered 'Urine (URINE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:48:55
User closed query 'Per CDM: A yes/no response is required for this field. Please update.' (Site from DM).		21 Oct 2020 17:47:48
Query 'Per CDM: A yes/no response is required for this field. Please update.' answered with 'done' (Site from DM).		16 Oct 2020 20:59:49
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error		16 Oct 2020 20:59:43
User opened query 'Per CDM: A yes/no response is required for this field. Please update.' (Site from DM).		16 Oct 2020 19:22:55
User closed query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).		09 Oct 2020 15:17:21
Query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'DONE' (Site from DM).		07 Oct 2020 17:12:15
User entered empty; reason for change Data Entry Error		07 Oct 2020 17:11:58
User opened query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).		07 Oct 2020 10:07:02
User entered 'Negative (NEGATIVE)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per CDM: A response is required for this field. Please update.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:31:32
Query 'Per CDM: A response is required for this field. Please update.' answered with 'updated' (Site from DM).		11 Nov 2020 18:28:28
User entered 'No (N)' reason for change: Data Entry Error		11 Nov 2020 18:28:22
User opened query 'Per CDM: A response is required for this field. Please update.' (Site from DM).		11 Nov 2020 15:09:26
User entered empty; reason for change Data Entry Error		09 Nov 2020 19:48:55
User entered 'No (N)' reason for change: Data Entry Error		16 Oct 2020 20:59:43
User entered empty; reason for change Data Entry Error		07 Oct 2020 17:11:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

US3442087

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:11:58
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

FDA-CBER-2022-1614-2401902

US3442087
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:11:58
User entered '16:25'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:07

US3442087

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered empty.	System	07 Oct 2020 17:11:58
User entered '25 Aug 2020 16:25'	System	26 Aug 2020 14:41:07

US3442087
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:24

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2401905

US3442087

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

US3442087

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

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)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2401907

US3442087
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:24
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 22:45:22

US3442087

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

US3442087
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:24

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '17:35'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '25 Aug 2020 17:35'	System	25 Aug 2020 22:45:22

US3442087
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:24

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:22

US3442087
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:24
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'ONCE'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2401913

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2401914

US3442087
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:46

US3442087

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '14:40'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:46

US3442087

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '25 Aug 2020 14:40'	System	25 Aug 2020 22:45:46

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '14:45'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '25 Aug 2020 14:45'	System	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:45:58

US3442087

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered empty.	System	25 Aug 2020 22:45:58

US3442087
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 22:46:03

US3442087

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '1'	System	25 Aug 2020 22:46:03

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:12:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1a327863-7bf3-4017-b8ad-81f89f86b88b'	System	25 Aug 2020 23:13:35
User entered 'Yes (Y)'	System	25 Aug 2020 23:13:35

FDA-CBER-2022-1614-2401931

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:20', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1a327863-7bf3-4017-b8ad-81f89f86b88b'	System	25 Aug 2020 23:13:35
User entered '97.3'	System	25 Aug 2020 23:13:35

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:24', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1a327863-7bf3-4017-b8ad-81f89f86b88b'	System	25 Aug 2020 23:13:35
User entered 'No (N)'	System	25 Aug 2020 23:13:35

FDA-CBER-2022-1614-2401933

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1a327863-7bf3-4017-b8ad-81f89f86b88b'	System	25 Aug 2020 23:13:35
User entered '25 Aug 2020 18:13'	System	25 Aug 2020 23:13:35

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 17:55'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 20:25'	System	25 Aug 2020 22:45:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:42:16', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ee3717bb-3d30-497a-bc58-0cc45135000d'	System	26 Aug 2020 02:42:36
User entered 'Yes (Y)'	System	26 Aug 2020 02:42:36

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:42:21', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ee3717bb-3d30-497a-bc58-0cc45135000d'	System	26 Aug 2020 02:42:36
User entered '98.2'	System	26 Aug 2020 02:42:36

FDA-CBER-2022-1614-2401939

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:42:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ee3717bb-3d30-497a-bc58-0cc45135000d'	System	26 Aug 2020 02:42:36
User entered 'No (N)'	System	26 Aug 2020 02:42:36

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:42:33', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ee3717bb-3d30-497a-bc58-0cc45135000d'	System	26 Aug 2020 02:42:36
User entered '25 Aug 2020 21:42'	System	26 Aug 2020 02:42:36

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 21:20'	System	25 Aug 2020 22:45:22

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2401943

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 2'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:04', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e8a7f123-acc1-4038-9b89-a885d159f7e3'	System	26 Aug 2020 17:01:43
User entered 'Yes (Y)'	System	26 Aug 2020 17:01:43

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:08', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e8a7f123-acc1-4038-9b89-a885d159f7e3'	System	26 Aug 2020 17:01:43
User entered '98.7'	System	26 Aug 2020 17:01:43

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:13', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e8a7f123-acc1-4038-9b89-a885d159f7e3'	System	26 Aug 2020 17:01:43
User entered 'No (N)'	System	26 Aug 2020 17:01:43

FDA-CBER-2022-1614-2401947

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:20', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e8a7f123-acc1-4038-9b89-a885d159f7e3'	System	26 Aug 2020 17:01:43
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 17:01:43

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 3'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:53:31', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3cb06ec6-708c-4377-b220-3f1596418ada'	System	27 Aug 2020 17:53:49
User entered 'Yes (Y)'	System	27 Aug 2020 17:53:49

FDA-CBER-2022-1614-2401952

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:53:36', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3cb06ec6-708c-4377-b220-3f1596418ada'	System	27 Aug 2020 17:53:49
User entered '98.7'	System	27 Aug 2020 17:53:49

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:24
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:53:42', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3cb06ec6-708c-4377-b220-3f1596418ada'	System	27 Aug 2020 17:53:49
User entered 'No (N)'	System	27 Aug 2020 17:53:49

FDA-CBER-2022-1614-2401954

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:53:45', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3cb06ec6-708c-4377-b220-3f1596418ada'	System	27 Aug 2020 17:53:49
User entered '27 Aug 2020 12:53'	System	27 Aug 2020 17:53:49

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 4'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:08:48', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5b2f34c5-322c-487e-b8e8-55546a6745bd'	System	28 Aug 2020 17:09:03
User entered 'Yes (Y)'	System	28 Aug 2020 17:09:03

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:08:53', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5b2f34c5-322c-487e-b8e8-55546a6745bd'	System	28 Aug 2020 17:09:03
User entered '98.8'	System	28 Aug 2020 17:09:03

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:08:56', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5b2f34c5-322c-487e-b8e8-55546a6745bd'	System	28 Aug 2020 17:09:03
User entered 'No (N)'	System	28 Aug 2020 17:09:03

FDA-CBER-2022-1614-2401961

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:08:59', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5b2f34c5-322c-487e-b8e8-55546a6745bd'	System	28 Aug 2020 17:09:03
User entered '28 Aug 2020 12:08'	System	28 Aug 2020 17:09:03

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 5'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:04', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '4de878b9-cb80-447c-b78c-f3da7f049925'	System	29 Aug 2020 21:20:19
User entered 'Yes (Y)'	System	29 Aug 2020 21:20:19

FDA-CBER-2022-1614-2401966

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:08', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '4de878b9-cb80-447c-b78c-f3da7f049925'	System	29 Aug 2020 21:20:19
User entered '98.7'	System	29 Aug 2020 21:20:19

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:11', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '4de878b9-cb80-447c-b78c-f3da7f049925'	System	29 Aug 2020 21:20:19
User entered 'No (N)'	System	29 Aug 2020 21:20:19

FDA-CBER-2022-1614-2401968

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:14', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '4de878b9-cb80-447c-b78c-f3da7f049925'	System	29 Aug 2020 21:20:19
User entered '29 Aug 2020 16:20'	System	29 Aug 2020 21:20:19

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 6'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:32', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e11e8a33-9989-4fed-9aa1-0d5c534f4171'	System	30 Aug 2020 17:00:50
User entered 'Yes (Y)'	System	30 Aug 2020 17:00:50

FDA-CBER-2022-1614-2401973

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:36', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e11e8a33-9989-4fed-9aa1-0d5c534f4171'	System	30 Aug 2020 17:00:50
User entered '98.7'	System	30 Aug 2020 17:00:50

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:40', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e11e8a33-9989-4fed-9aa1-0d5c534f4171'	System	30 Aug 2020 17:00:50
User entered 'No (N)'	System	30 Aug 2020 17:00:50

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:45', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e11e8a33-9989-4fed-9aa1-0d5c534f4171'	System	30 Aug 2020 17:00:50
User entered '30 Aug 2020 12:00'	System	30 Aug 2020 17:00:50

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 7'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:04:04', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'd0f9bf67-3341-4555-860b-19af70d3d2b8'	System	31 Aug 2020 17:15:48
User entered 'Yes (Y)'	System	31 Aug 2020 17:15:48

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:04:09', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'd0f9bf67-3341-4555-860b-19af70d3d2b8'	System	31 Aug 2020 17:15:48
User entered '98.5'	System	31 Aug 2020 17:15:48

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:04:14', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'd0f9bf67-3341-4555-860b-19af70d3d2b8'	System	31 Aug 2020 17:15:48
User entered 'No (N)'	System	31 Aug 2020 17:15:48

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:04:26', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'd0f9bf67-3341-4555-860b-19af70d3d2b8'	System	31 Aug 2020 17:15:48
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 17:15:48

US3442087

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:38', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '18836091-298f-48b5-b25c-3a6307cd7254'	System	25 Aug 2020 23:14:12
User entered 'None (1)'	System	25 Aug 2020 23:14:12

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:52', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '18836091-298f-48b5-b25c-3a6307cd7254'	System	25 Aug 2020 23:14:12
User entered 'No (N)'	System	25 Aug 2020 23:14:12

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:13:55', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '18836091-298f-48b5-b25c-3a6307cd7254'	System	25 Aug 2020 23:14:12
User entered 'No (N)'	System	25 Aug 2020 23:14:12

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:03', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '18836091-298f-48b5-b25c-3a6307cd7254'	System	25 Aug 2020 23:14:12
User entered 'None (1)'	System	25 Aug 2020 23:14:12

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:06', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '18836091-298f-48b5-b25c-3a6307cd7254'	System	25 Aug 2020 23:14:12
User entered '25 Aug 2020 18:14'	System	25 Aug 2020 23:14:12

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 17:55'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 20:25'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:03', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ae9b68c-0b6a-409b-90ac-8c12a2feaa6d'	System	26 Aug 2020 02:43:47
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 02:43:47

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:06', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ae9b68c-0b6a-409b-90ac-8c12a2feaa6d'	System	26 Aug 2020 02:43:47
User entered 'No (N)'	System	26 Aug 2020 02:43:47

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:15', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ae9b68c-0b6a-409b-90ac-8c12a2feaa6d'	System	26 Aug 2020 02:43:47
User entered 'No (N)'	System	26 Aug 2020 02:43:47

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:24', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ae9b68c-0b6a-409b-90ac-8c12a2feaa6d'	System	26 Aug 2020 02:43:47
User entered 'None (1)'	System	26 Aug 2020 02:43:47

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:35', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ae9b68c-0b6a-409b-90ac-8c12a2feaa6d'	System	26 Aug 2020 02:43:47
User entered '25 Aug 2020 21:43'	System	26 Aug 2020 02:43:47

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 21:20'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 2'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '280410bd-3d04-4a70-bc61-76750ac358f5'	System	26 Aug 2020 17:02:16
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:02:16

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:24
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:31', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '280410bd-3d04-4a70-bc61-76750ac358f5'	System	26 Aug 2020 17:02:16
User entered 'No (N)'	System	26 Aug 2020 17:02:16

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US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:52', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '280410bd-3d04-4a70-bc61-76750ac358f5'	System	26 Aug 2020 17:02:16
User entered 'No (N)'	System	26 Aug 2020 17:02:16

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:01:56', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '280410bd-3d04-4a70-bc61-76750ac358f5'	System	26 Aug 2020 17:02:16
User entered 'None (1)'	System	26 Aug 2020 17:02:16

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:01', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '280410bd-3d04-4a70-bc61-76750ac358f5'	System	26 Aug 2020 17:02:16
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 17:02:16

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 3'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:09', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9ec51263-050a-4eba-8285-12b60e714e4c'	System	27 Aug 2020 17:54:32
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 17:54:32

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:17', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9ec51263-050a-4eba-8285-12b60e714e4c'	System	27 Aug 2020 17:54:32
User entered 'No (N)'	System	27 Aug 2020 17:54:32

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:21', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9ec51263-050a-4eba-8285-12b60e714e4c'	System	27 Aug 2020 17:54:32
User entered 'No (N)'	System	27 Aug 2020 17:54:32

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:25', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9ec51263-050a-4eba-8285-12b60e714e4c'	System	27 Aug 2020 17:54:32
User entered 'None (1)'	System	27 Aug 2020 17:54:32

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:29', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9ec51263-050a-4eba-8285-12b60e714e4c'	System	27 Aug 2020 17:54:32
User entered '27 Aug 2020 12:54'	System	27 Aug 2020 17:54:32

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 4'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:05', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ea894bc8-2d3c-47a6-95c8-8f09ac2f0030'	System	28 Aug 2020 17:09:25
User entered 'None (1)'	System	28 Aug 2020 17:09:25

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:08', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ea894bc8-2d3c-47a6-95c8-8f09ac2f0030'	System	28 Aug 2020 17:09:25
User entered 'No (N)'	System	28 Aug 2020 17:09:25

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ea894bc8-2d3c-47a6-95c8-8f09ac2f0030'	System	28 Aug 2020 17:09:25
User entered 'No (N)'	System	28 Aug 2020 17:09:25

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US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:16', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ea894bc8-2d3c-47a6-95c8-8f09ac2f0030'	System	28 Aug 2020 17:09:25
User entered 'None (1)'	System	28 Aug 2020 17:09:25

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US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:19', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ea894bc8-2d3c-47a6-95c8-8f09ac2f0030'	System	28 Aug 2020 17:09:25
User entered '28 Aug 2020 12:09'	System	28 Aug 2020 17:09:25

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US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 5'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:18', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '82adb3e2-9546-4c42-a53b-cdae823bb966'	System	29 Aug 2020 21:20:35
User entered 'None (1)'	System	29 Aug 2020 21:20:35

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US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:21', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '82adb3e2-9546-4c42-a53b-cdae823bb966'	System	29 Aug 2020 21:20:35
User entered 'No (N)'	System	29 Aug 2020 21:20:35

FDA-CBER-2022-1614-2402028

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:26', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '82adb3e2-9546-4c42-a53b-cdae823bb966'	System	29 Aug 2020 21:20:35
User entered 'No (N)'	System	29 Aug 2020 21:20:35

FDA-CBER-2022-1614-2402029

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:29', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '82adb3e2-9546-4c42-a53b-cdae823bb966'	System	29 Aug 2020 21:20:35
User entered 'None (1)'	System	29 Aug 2020 21:20:35

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:32', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '82adb3e2-9546-4c42-a53b-cdae823bb966'	System	29 Aug 2020 21:20:35
User entered '29 Aug 2020 16:20'	System	29 Aug 2020 21:20:35

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 6'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:49', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cbc7f2c8-d2ba-4b77-ae39-99a7e9b26627'	System	30 Aug 2020 17:01:07
User entered 'None (1)'	System	30 Aug 2020 17:01:07

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:51', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cbc7f2c8-d2ba-4b77-ae39-99a7e9b26627'	System	30 Aug 2020 17:01:07
User entered 'No (N)'	System	30 Aug 2020 17:01:07

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:53', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cbc7f2c8-d2ba-4b77-ae39-99a7e9b26627'	System	30 Aug 2020 17:01:07
User entered 'No (N)'	System	30 Aug 2020 17:01:07

FDA-CBER-2022-1614-2402037

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:55', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cbc7f2c8-d2ba-4b77-ae39-99a7e9b26627'	System	30 Aug 2020 17:01:07
User entered 'None (1)'	System	30 Aug 2020 17:01:07

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:00:57', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cbc7f2c8-d2ba-4b77-ae39-99a7e9b26627'	System	30 Aug 2020 17:01:07
User entered '30 Aug 2020 12:00'	System	30 Aug 2020 17:01:07

FDA-CBER-2022-1614-2402039

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 7'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '89f9527a-b658-4797-878d-0b57758b3896'	System	31 Aug 2020 17:16:02
User entered 'None (1)'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:13', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '89f9527a-b658-4797-878d-0b57758b3896'	System	31 Aug 2020 17:16:02
User entered 'No (N)'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:15', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '89f9527a-b658-4797-878d-0b57758b3896'	System	31 Aug 2020 17:16:02
User entered 'No (N)'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:18', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '89f9527a-b658-4797-878d-0b57758b3896'	System	31 Aug 2020 17:16:02
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:23', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '89f9527a-b658-4797-878d-0b57758b3896'	System	31 Aug 2020 17:16:02
User entered '31 Aug 2020 12:05'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:13', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:17', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:21', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:25', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:29', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

FDA-CBER-2022-1614-2402055

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:32', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'None (0)'	System	25 Aug 2020 23:14:48

FDA-CBER-2022-1614-2402056

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:40', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered 'No (N)'	System	25 Aug 2020 23:14:48

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T18:14:42', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '9134bb34-768c-463d-af76-02552de545b7'	System	25 Aug 2020 23:14:48
User entered '25 Aug 2020 18:14'	System	25 Aug 2020 23:14:48

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 17:55'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 20:25'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:40', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:44', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:43:54', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:44:03', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:44:06', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:44:15', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'None (0)'	System	26 Aug 2020 02:44:30

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:44:22', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered 'No (N)'	System	26 Aug 2020 02:44:30

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:24
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-25T21:44:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '264eff39-316c-48a5-bca8-8f0bb3b35ed9'	System	26 Aug 2020 02:44:30
User entered '25 Aug 2020 21:44'	System	26 Aug 2020 02:44:30

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '25 Aug 2020 21:20'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 2'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:06', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:09', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:14', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:17', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:20', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:23', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'None (0)'	System	26 Aug 2020 17:02:41

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:30', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered 'No (N)'	System	26 Aug 2020 17:02:41

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-26T12:02:35', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8bad46f4-34df-49e5-9ac5-ba57fcb9e7b2'	System	26 Aug 2020 17:02:41
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 17:02:41

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 3'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:34', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'None (0)'	System	27 Aug 2020 17:55:11

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:43', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:55:11

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:47', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'None (0)'	System	27 Aug 2020 17:55:11

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:49', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'None (0)'	System	27 Aug 2020 17:55:11

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:55', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'None (0)'	System	27 Aug 2020 17:55:11

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:54:57', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'None (0)'	System	27 Aug 2020 17:55:11

FDA-CBER-2022-1614-2402089

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:55:04', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered 'No (N)'	System	27 Aug 2020 17:55:11

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-27T12:55:08', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '84cc2b94-c601-4f33-8fa1-2ee0d2f6a55d'	System	27 Aug 2020 17:55:11
User entered '27 Aug 2020 12:55'	System	27 Aug 2020 17:55:11

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2402093

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 4'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:23', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:25', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

FDA-CBER-2022-1614-2402097

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:29', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:31', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

FDA-CBER-2022-1614-2402099

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:33', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'None (0)'	System	28 Aug 2020 17:09:50

FDA-CBER-2022-1614-2402100

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:43', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered 'No (N)'	System	28 Aug 2020 17:09:50

FDA-CBER-2022-1614-2402101

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-28T12:09:46', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '935cfe91-6dfc-4b58-b37b-46d78b2b0137'	System	28 Aug 2020 17:09:50
User entered '28 Aug 2020 12:09'	System	28 Aug 2020 17:09:50

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 5'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:21:07', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'No interference with activity (1)'	System	29 Aug 2020 21:21:12

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:46', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'None (0)'	System	29 Aug 2020 21:21:12

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US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:49', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'None (0)'	System	29 Aug 2020 21:21:12

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:52', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'None (0)'	System	29 Aug 2020 21:21:12

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:54', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'None (0)'	System	29 Aug 2020 21:21:12

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:20:57', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'None (0)'	System	29 Aug 2020 21:21:12

FDA-CBER-2022-1614-2402111

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:21:02', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered 'No (N)'	System	29 Aug 2020 21:21:12

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-29T16:21:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ba04411c-f987-4a40-b4f5-111983cb6e48'	System	29 Aug 2020 21:21:12
User entered '29 Aug 2020 16:21'	System	29 Aug 2020 21:21:12

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 6'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:02', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:05', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:07', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:08', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:11', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'None (0)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:17', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered 'No (N)'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-30T12:01:20', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '3feb8d10-55b6-46e9-aab4-815dde9180b6'	System	30 Aug 2020 17:01:25
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:25

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 7'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:27', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'None (0)'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:32', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'No interference with activity (1)'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:36', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'None (0)'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:39', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'None (0)'	System	31 Aug 2020 17:16:17

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:41', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'None (0)'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:43', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'None (0)'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:49', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered 'No (N)'	System	31 Aug 2020 17:16:17

US3442087

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-08-31T12:05:52', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '36efcf05-cde7-47ed-92fc-f4333f5844d8'	System	31 Aug 2020 17:16:17
User entered '31 Aug 2020 12:05'	System	31 Aug 2020 17:16:17

FDA-CBER-2022-1614-2402135

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2402136

US3442087
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	31 Aug 2020 17:16:17
User entered 'Day 8'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:42:24

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:58:38', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ec98e240-27d0-40f1-8509-07d75994a9db'	System	02 Sep 2020 11:58:46
User entered 'None (0)'	System	02 Sep 2020 11:58:46

FDA-CBER-2022-1614-2402139

US3442087
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:58:41', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ec98e240-27d0-40f1-8509-07d75994a9db'	System	02 Sep 2020 11:58:46
User entered '02 Sep 2020 06:58'	System	02 Sep 2020 11:58:46

US3442087

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:16:17

US3442087

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:42:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:16:17

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	31 Aug 2020 17:16:17
DataPoint Inactivated.	System	31 Aug 2020 17:16:02
Data entry locked.	System	31 Aug 2020 17:16:02
User entered 'Day 8'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:58:48', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5a98500d-acdf-4eee-b210-4051b28f3443'	System	02 Sep 2020 11:58:54
User entered 'No (N)'	System	02 Sep 2020 11:58:54
DataPoint Activated.	System	31 Aug 2020 17:16:17
DataPoint Inactivated.	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:58:51', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '5a98500d-acdf-4eee-b210-4051b28f3443'	System	02 Sep 2020 11:58:54
User entered '02 Sep 2020 06:58'	System	02 Sep 2020 11:58:54
DataPoint Activated.	System	31 Aug 2020 17:16:17
DataPoint Inactivated.	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	31 Aug 2020 17:16:17
DataPoint Inactivated.	System	31 Aug 2020 17:16:02
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	31 Aug 2020 17:16:17
DataPoint Inactivated.	System	31 Aug 2020 17:16:02
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	02 Sep 2020 11:59:09
DataPoint Inactivated.	System	02 Sep 2020 11:58:46
Data entry locked.	System	31 Aug 2020 17:16:02
User entered 'Day 9'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T12:16:13', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'c467a746-81c6-4d31-ac63-77da36615349'	System	02 Sep 2020 17:16:25
User entered 'No (N)'	System	02 Sep 2020 17:16:25
DataPoint Activated.	System	02 Sep 2020 11:59:09
DataPoint Inactivated.	System	02 Sep 2020 11:58:46

FDA-CBER-2022-1614-2402149

US3442087

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:42:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T12:16:16', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'c467a746-81c6-4d31-ac63-77da36615349'	System	02 Sep 2020 17:16:25
User entered '02 Sep 2020 12:16'	System	02 Sep 2020 17:16:25
DataPoint Activated.	System	02 Sep 2020 11:59:09
DataPoint Inactivated.	System	02 Sep 2020 11:58:46

US3442087

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:42:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	02 Sep 2020 11:59:09
DataPoint Inactivated.	System	02 Sep 2020 11:58:46
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:42:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
DataPoint Activated.	System	02 Sep 2020 11:59:09
DataPoint Inactivated.	System	02 Sep 2020 11:58:46
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	31 Aug 2020 17:16:02
User entered 'Day 8'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 17:42:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:59:01', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '13102b48-bf68-4574-9b89-9a3880ffe227'	System	02 Sep 2020 11:59:09
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 11:59:09

FDA-CBER-2022-1614-2402154

US3442087
Folder: Diary Dose 1 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T06:59:04', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '13102b48-bf68-4574-9b89-9a3880ffe227'	System	02 Sep 2020 11:59:09
User entered '02 Sep 2020 06:59'	System	02 Sep 2020 11:59:09

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 17:42:24

PC Open Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:16:02

PC Close Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:16:02

US3442087
Folder: Diary Dose 1 (1)
Form: Underarm Gland_Day(9)
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
Data entry locked.	System	31 Aug 2020 17:16:02
User entered 'Day 9'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T12:16:19', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '336e68fc-1d38-4fbc-8284-f03b68f7bf22'	System	02 Sep 2020 17:16:27
User entered 'None (1)'	System	02 Sep 2020 17:16:27

US3442087
Folder: Diary Dose 1 (1)
Form: Underarm Gland_Day(9)
Generated On: 09 Jun 2021 17:42:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-09-02T12:16:22', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '336e68fc-1d38-4fbc-8284-f03b68f7bf22'	System	02 Sep 2020 17:16:27
User entered '02 Sep 2020 12:16'	System	02 Sep 2020 17:16:27

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 09 Jun 2021 17:42:24

PC Open Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:16:02

US3442087

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 09 Jun 2021 17:42:24

PC Close Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:13:45
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:16:02

US3442087
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:18:43

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:18:43

US3442087

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:18:43

US3442087
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:18:43

US3442087
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:18:50

US3442087
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '1'	System	01 Sep 2020 17:18:50

US3442087
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:50:33

US3442087

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:50:33

US3442087
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 20:50:33

US3442087
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:50:33

US3442087
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:50:40

US3442087

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:29:12
User entered '1'	System	08 Sep 2020 20:50:40

Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 21:57:56

US3442087

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 21:57:56

US3442087
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:57:56

US3442087
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 21:57:56

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:58:01

FDA-CBER-2022-1614-2402179

US3442087
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:34
User entered '1'	System	15 Sep 2020 21:58:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:14:02

US3442087
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 22:14:02

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:14:02

FDA-CBER-2022-1614-2402183

US3442087
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'VISIT2'	System	14 Oct 2020 22:14:02

US3442087
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:24
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Pre-Dose (PREDOSE)'		14 Oct 2020 22:14:36

FDA-CBER-2022-1614-2402185

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '08:39'	(b) (4), (b) (6)	14 Oct 2020 22:14:36

FDA-CBER-2022-1614-2402188

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '28 Sep 2020 08:39'	System	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '97.6' F	(b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:14:36

FDA-CBER-2022-1614-2402191

US3442087
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '73'	(b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'bpm'	System	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '14'	(b) (4), (b) (6)	14 Oct 2020 22:14:36

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'breaths/min'	System	14 Oct 2020 22:14:36

FDA-CBER-2022-1614-2402196

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '116'	(b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '75'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	14 Oct 2020 22:14:36

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Post-Dose (POSTDOSE)'		14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:17:19

FDA-CBER-2022-1614-2402205

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:17:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:17:19

US3442087

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:17:19

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:24
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:15:17

FDA-CBER-2022-1614-2402217

US3442087

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:15:17

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 22:14:53

FDA-CBER-2022-1614-2402220

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:42:24
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:14:53

US3442087
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:24

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:19:27

US3442087
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:24
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Per CDM: Reason for dose not given is 'other' under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Withdrawal of consent by participant '. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 19:45:27
Query 'Per CDM: Reason for dose not given is 'other' under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Withdrawal of consent by participant '. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' answered with 'updated.' (Site from DM).	Oluwatosin Akingbala (b) (4)	07 Apr 2021 22:59:33
Signature has been broken.	Oluwatosin Akingbala (b) (4)	07 Apr 2021 22:59:07
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	07 Apr 2021 22:59:07
User opened query 'Per CDM: Reason for dose not given is 'other' under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Withdrawal of consent by participant '. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:35:16
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 22:19:27

FDA-CBER-2022-1614-2402228

US3442087

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'subject did not withdraw consent, but wished to withdraw from receiving second dosing.'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:19:27

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:19:27

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:27

FDA-CBER-2022-1614-2402231

US3442087
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:24

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:27

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:19:27

FDA-CBER-2022-1614-2402233

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:27

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:19:27

FDA-CBER-2022-1614-2402235

US3442087
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:24
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:19:27

US3442087
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:15:42

US3442087

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:15:42

US3442087

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '08:50'	(b) (4), (b) (6)	14 Oct 2020 22:15:42

US3442087

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '28 Sep 2020 08:50'	System	14 Oct 2020 22:15:42

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:16:57

US3442087

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Oct 2020 22:16:57

US3442087

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:16:57

FDA-CBER-2022-1614-2402243

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '08:55'	(b) (4), (b) (6)	14 Oct 2020 22:16:57

US3442087

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '28 Sep 2020 08:55'	System	14 Oct 2020 22:16:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Oct 2020 22:16:57

FDA-CBER-2022-1614-2402246

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:16:57

FDA-CBER-2022-1614-2402247

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:16:57

FDA-CBER-2022-1614-2402248

US3442087

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	14 Oct 2020 22:16:57

US3442087
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Please change the response to NO as the subject is discontinued ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:57:16
Query 'Please change the response to NO as the subject is discontinued ' answered with 'subject discontinued from second dose but is still participating in the trial' (Site from CRA).		25 Jan 2021 18:59:58
User opened query 'Please change the response to NO as the subject is discontinued ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 20:14:19
User entered 'Yes (Y)'		14 Oct 2020 22:19:43

US3442087

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1'	System	14 Oct 2020 22:19:43

US3442087
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:19:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '5 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:19:58

FDA-CBER-2022-1614-2402253

US3442087

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:19:58

FDA-CBER-2022-1614-2402254

US3442087
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:58

US3442087
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:20:05

US3442087
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '1'	System	14 Oct 2020 22:20:05

US3442087
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:20:15

US3442087

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:20:15

US3442087
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:20:15

FDA-CBER-2022-1614-2402260

US3442087
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:20:15

US3442087
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:20:21

US3442087

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '1'	System	14 Oct 2020 22:20:21

US3442087
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 19:21:00

US3442087
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 19:21:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 19:21:00

FDA-CBER-2022-1614-2402266

US3442087
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 19:21:00

US3442087
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:21:05

US3442087

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '1'	System	19 Oct 2020 19:21:05

US3442087
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:39:48

US3442087
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:39:48

US3442087

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 14:39:48

FDA-CBER-2022-1614-2402272

US3442087
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered 'VISIT3'	System	23 Oct 2020 14:39:48

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered empty.	System	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered empty.	System	23 Oct 2020 14:39:56

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

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US3442087
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered empty.	System	23 Oct 2020 14:39:56

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered empty.	System	23 Oct 2020 14:39:56

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:39:56

FDA-CBER-2022-1614-2402287

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered empty.	System	23 Oct 2020 14:39:56

FDA-CBER-2022-1614-2402288

US3442087

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:40:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:40:15

US3442087
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:40:48

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 14:40:48

US3442087

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '08:11'	(b) (4), (b) (6)	23 Oct 2020 14:40:48

US3442087

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '23 Oct 2020 08:11'	System	23 Oct 2020 14:40:48

US3442087

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:40:59

US3442087
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '1'	System	23 Oct 2020 14:40:59

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 64'	System	25 Aug 2020 22:45:22

FDA-CBER-2022-1614-2402299

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

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US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 22:45:22

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 71'	System	25 Aug 2020 22:45:22

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 22:45:22

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered 'Day 78'	System	25 Aug 2020 22:45:22

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 22:45:22

US3442087

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:46:30
Data entry locked.	System	25 Aug 2020 22:45:22
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 22:45:22

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-11-20T12:20:59', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '43b01f37-c346-49a0-8339-b8be4d8c8aa6'	System	20 Nov 2020 18:21:18
User entered 'No (N)'	System	20 Nov 2020 18:21:18

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-11-20T12:21:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '43b01f37-c346-49a0-8339-b8be4d8c8aa6'	System	20 Nov 2020 18:21:18
User entered 'No (N)'	System	20 Nov 2020 18:21:18

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-11-20T12:21:14', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '43b01f37-c346-49a0-8339-b8be4d8c8aa6'	System	20 Nov 2020 18:21:18
User entered '20 Nov 2020 12:21:14'	System	20 Nov 2020 18:21:18

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:46:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-11-26T00:16:30', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ac67710d-0b7d-4d07-8888-289abe33c604'	System	26 Nov 2020 06:17:01
User entered 'No (N)'	System	26 Nov 2020 06:17:01

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-11-26T00:16:54', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ac67710d-0b7d-4d07-8888-289abe33c604'	System	26 Nov 2020 06:17:01
User entered 'No (N)'	System	26 Nov 2020 06:17:01

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-11-26T00:16:58', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ac67710d-0b7d-4d07-8888-289abe33c604'	System	26 Nov 2020 06:17:01
User entered '26 Nov 2020 00:16:58'	System	26 Nov 2020 06:17:01

FDA-CBER-2022-1614-2402392

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-12-03T16:55:49', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ba97bd2-0cfe-4c7e-aa86-1034d97d0b1f'	System	03 Dec 2020 22:56:02
User entered 'No (N)'	System	03 Dec 2020 22:56:02

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-12-03T16:55:54', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ba97bd2-0cfe-4c7e-aa86-1034d97d0b1f'	System	03 Dec 2020 22:56:02
User entered 'No (N)'	System	03 Dec 2020 22:56:02

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-12-03T16:55:59', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '0ba97bd2-0cfe-4c7e-aa86-1034d97d0b1f'	System	03 Dec 2020 22:56:02
User entered '03 Dec 2020 16:55:59'	System	03 Dec 2020 22:56:02

FDA-CBER-2022-1614-2402398

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-12-12T15:24:09', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b87bfe13-5a5b-4a4b-a556-da365e7d0f00'	System	12 Dec 2020 21:24:20
User entered 'No (N)'	System	12 Dec 2020 21:24:20

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-12-12T15:24:13', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b87bfe13-5a5b-4a4b-a556-da365e7d0f00'	System	12 Dec 2020 21:24:20
User entered 'No (N)'	System	12 Dec 2020 21:24:20

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-12-12T15:24:15', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b87bfe13-5a5b-4a4b-a556-da365e7d0f00'	System	12 Dec 2020 21:24:20
User entered '12 Dec 2020 15:24:15'	System	12 Dec 2020 21:24:20

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-12-17T07:25:25', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '2b08a554-fafb-4a96-b24b-edba33a9b7cd'	System	17 Dec 2020 13:25:47
User entered 'No (N)'	System	17 Dec 2020 13:25:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-12-17T07:25:39', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '2b08a554-fafb-4a96-b24b-edba33a9b7cd'	System	17 Dec 2020 13:25:47
User entered 'No (N)'	System	17 Dec 2020 13:25:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-12-17T07:25:43', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '2b08a554-fafb-4a96-b24b-edba33a9b7cd'	System	17 Dec 2020 13:25:47
User entered '17 Dec 2020 07:25:43'	System	17 Dec 2020 13:25:47

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2020-12-24T00:01:59', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e22fb51c-5bbe-413a-b01d-8ee8938608bc'	System	24 Dec 2020 06:02:58
User entered 'No (N)'	System	24 Dec 2020 06:02:58

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2020-12-24T00:02:11', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e22fb51c-5bbe-413a-b01d-8ee8938608bc'	System	24 Dec 2020 06:02:58
User entered 'Yes (Y)'	System	24 Dec 2020 06:02:58

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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 (7b2f97654d715477)', Time: '2020-12-24T00:02:37', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e22fb51c-5bbe-413a-b01d-8ee8938608bc'	System	24 Dec 2020 06:02:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 06:02:58

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2020-12-24T00:02:40', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'e22fb51c-5bbe-413a-b01d-8ee8938608bc'	System	24 Dec 2020 06:02:58
User entered '24 Dec 2020 00:02:40'	System	24 Dec 2020 06:02:58

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:46:30

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US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-01-18T20:04:40', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '56242252-6a32-47b8-a373-effd75bc3005'	System	19 Jan 2021 02:04:56
User entered 'No (N)'	System	19 Jan 2021 02:04:56

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-01-18T20:04:44', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '56242252-6a32-47b8-a373-effd75bc3005'	System	19 Jan 2021 02:04:56
User entered 'No (N)'	System	19 Jan 2021 02:04:56

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-01-18T20:04:47', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '56242252-6a32-47b8-a373-effd75bc3005'	System	19 Jan 2021 02:04:56
User entered '18 Jan 2021 20:04:47'	System	19 Jan 2021 02:04:56

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-01-25T14:49:53', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '72874006-c85e-467b-becc-7041c5d937ec'	System	25 Jan 2021 20:50:08
User entered 'No (N)'	System	25 Jan 2021 20:50:08

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-01-25T14:49:57', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '72874006-c85e-467b-becc-7041c5d937ec'	System	25 Jan 2021 20:50:08
User entered 'No (N)'	System	25 Jan 2021 20:50:08

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-01-25T14:50:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '72874006-c85e-467b-becc-7041c5d937ec'	System	25 Jan 2021 20:50:08
User entered '25 Jan 2021 14:50:00'	System	25 Jan 2021 20:50:08

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:46:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-01-28T06:34:54', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered 'Yes (Y)'	System	28 Jan 2021 12:36:04

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-01-28T06:34:25', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered 'No (N)'	System	28 Jan 2021 12:36:04

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-01-28T06:35:10', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered 'No (N)'	System	28 Jan 2021 12:36:04

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-01-28T06:35:37', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered 'Yes (Y)'	System	28 Jan 2021 12:36:04

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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 (7b2f97654d715477)', Time: '2021-01-28T06:35:45', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 12:36:04

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-01-28T06:35:50', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1530eb76-082f-43e9-a96b-60131b21a458'	System	28 Jan 2021 12:36:04
User entered '28 Jan 2021 06:35:50'	System	28 Jan 2021 12:36:04

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-02-07T17:00:26', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '395f5354-2756-48df-998b-c4c790920799'	System	07 Feb 2021 23:00:58
User entered 'No (N)'	System	07 Feb 2021 23:00:58

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-02-07T17:00:30', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '395f5354-2756-48df-998b-c4c790920799'	System	07 Feb 2021 23:00:58
User entered 'No (N)'	System	07 Feb 2021 23:00:58

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-02-07T17:00:33', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '395f5354-2756-48df-998b-c4c790920799'	System	07 Feb 2021 23:00:58
User entered '07 Feb 2021 17:00:33'	System	07 Feb 2021 23:00:58

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-02-11T06:53:31', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'afac0353-73a6-4673-8962-94ebf6cb68e3'	System	11 Feb 2021 12:53:43
User entered 'No (N)'	System	11 Feb 2021 12:53:43

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-02-11T06:53:35', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'afac0353-73a6-4673-8962-94ebf6cb68e3'	System	11 Feb 2021 12:53:43
User entered 'No (N)'	System	11 Feb 2021 12:53:43

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-02-11T06:53:38', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'afac0353-73a6-4673-8962-94ebf6cb68e3'	System	11 Feb 2021 12:53:43
User entered '11 Feb 2021 06:53:38'	System	11 Feb 2021 12:53:43

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-02-22T17:07:53', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ffeaf664-bb3b-4835-8288-6f49a72d7749'	System	22 Feb 2021 23:12:24
User entered 'No (N)'	System	22 Feb 2021 23:12:24

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-02-22T17:07:55', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ffeaf664-bb3b-4835-8288-6f49a72d7749'	System	22 Feb 2021 23:12:24
User entered 'No (N)'	System	22 Feb 2021 23:12:24

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-02-22T17:07:58', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'ffeaf664-bb3b-4835-8288-6f49a72d7749'	System	22 Feb 2021 23:12:24
User entered '22 Feb 2021 17:07:58'	System	22 Feb 2021 23:12:24

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-02-25T07:08:39-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '71cea4c7-6721-49cd-8919-d9213a4927a6'	System	25 Feb 2021 17:27:50
User entered 'No (N)'	System	25 Feb 2021 17:27:50

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-02-25T07:08:45-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '71cea4c7-6721-49cd-8919-d9213a4927a6'	System	25 Feb 2021 17:27:50
User entered 'No (N)'	System	25 Feb 2021 17:27:50

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-02-25T07:08:47-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '71cea4c7-6721-49cd-8919-d9213a4927a6'	System	25 Feb 2021 17:27:50
User entered '25 Feb 2021 07:08:47'	System	25 Feb 2021 17:27:50

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-05T06:08:02-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'bf905d29-b668-45e1-a027-87e240082732'	System	05 Mar 2021 12:08:17
User entered 'No (N)'	System	05 Mar 2021 12:08:17

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-03-05T06:08:07-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'bf905d29-b668-45e1-a027-87e240082732'	System	05 Mar 2021 12:08:17
User entered 'No (N)'	System	05 Mar 2021 12:08:17

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-05T06:08:10-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'bf905d29-b668-45e1-a027-87e240082732'	System	05 Mar 2021 12:08:17
User entered '05 Mar 2021 06:08:10'	System	05 Mar 2021 12:08:17

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-11T07:03:34-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b84e9c2b-86c7-421d-8878-19309bd80094'	System	11 Mar 2021 13:04:06
User entered 'Yes (Y)'	System	11 Mar 2021 13:04:06

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US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-03-11T07:03:38-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b84e9c2b-86c7-421d-8878-19309bd80094'	System	11 Mar 2021 13:04:06
User entered 'No (N)'	System	11 Mar 2021 13:04:06

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-11T07:03:42-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b84e9c2b-86c7-421d-8878-19309bd80094'	System	11 Mar 2021 13:04:06
User entered 'No (N)'	System	11 Mar 2021 13:04:06

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-11T07:03:49-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b84e9c2b-86c7-421d-8878-19309bd80094'	System	11 Mar 2021 13:04:06
User entered 'No (N)'	System	11 Mar 2021 13:04:06

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-11T07:03:57-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'b84e9c2b-86c7-421d-8878-19309bd80094'	System	11 Mar 2021 13:04:06
User entered '11 Mar 2021 07:03:57'	System	11 Mar 2021 13:04:06

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-18T07:43:33-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '49d5d534-a5a7-4262-9692-a10a90627d63'	System	18 Mar 2021 12:44:01
User entered 'No (N)'	System	18 Mar 2021 12:44:01

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-03-18T07:43:41-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '49d5d534-a5a7-4262-9692-a10a90627d63'	System	18 Mar 2021 12:44:01
User entered 'No (N)'	System	18 Mar 2021 12:44:01

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-18T07:43:44-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '49d5d534-a5a7-4262-9692-a10a90627d63'	System	18 Mar 2021 12:44:01
User entered '18 Mar 2021 07:43:44'	System	18 Mar 2021 12:44:01

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

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 (7b2f97654d715477)', Time: '2021-03-25T05:48:00-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8b37fca0-3c01-40d3-a0c8-644926f921a1'	System	25 Mar 2021 10:48:11
User entered 'No (N)'	System	25 Mar 2021 10:48:11

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (7b2f97654d715477)', Time: '2021-03-25T05:48:04-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8b37fca0-3c01-40d3-a0c8-644926f921a1'	System	25 Mar 2021 10:48:11
User entered 'No (N)'	System	25 Mar 2021 10:48:11

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-25T05:48:07-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8b37fca0-3c01-40d3-a0c8-644926f921a1'	System	25 Mar 2021 10:48:11
User entered '25 Mar 2021 05:48:07'	System	25 Mar 2021 10:48:11

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-01T06:43:08-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8ee753a7-427c-4bb5-a768-733e448f93df'	System	01 Apr 2021 11:43:20
User entered 'No (N)'	System	01 Apr 2021 11:43:20

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (ac58117af1c33a14)', Time: '2021-04-01T06:43:15-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8ee753a7-427c-4bb5-a768-733e448f93df'	System	01 Apr 2021 11:43:20
User entered 'No (N)'	System	01 Apr 2021 11:43:20

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac58117af1c33a14)', Time: '2021-04-01T06:43:18-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '8ee753a7-427c-4bb5-a768-733e448f93df'	System	01 Apr 2021 11:43:20
User entered '01 Apr 2021 06:43:18'	System	01 Apr 2021 11:43:20

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-08T07:53:00-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered 'Yes (Y)'	System	08 Apr 2021 12:53:42

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (ac58117af1c33a14)', Time: '2021-04-08T07:53:03-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered 'No (N)'	System	08 Apr 2021 12:53:42

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-08T07:53:14-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered 'No (N)'	System	08 Apr 2021 12:53:42

FDA-CBER-2022-1614-2402506

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-08T07:53:22-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered 'Yes (Y)'	System	08 Apr 2021 12:53:42

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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 (ac58117af1c33a14)', Time: '2021-04-08T07:53:28-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 12:53:42

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac58117af1c33a14)', Time: '2021-04-08T07:53:31-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f8bc0d5c-c1d8-4634-960c-4305555be334'	System	08 Apr 2021 12:53:42
User entered '08 Apr 2021 07:53:31'	System	08 Apr 2021 12:53:42

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-15T06:51:23-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cc43fd02-d651-4180-b64d-0e46a8017c3e'	System	15 Apr 2021 11:51:34
User entered 'No (N)'	System	15 Apr 2021 11:51:34

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (ac58117af1c33a14)', Time: '2021-04-15T06:51:27-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cc43fd02-d651-4180-b64d-0e46a8017c3e'	System	15 Apr 2021 11:51:34
User entered 'No (N)'	System	15 Apr 2021 11:51:34

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac58117af1c33a14)', Time: '2021-04-15T06:51:30-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'cc43fd02-d651-4180-b64d-0e46a8017c3e'	System	15 Apr 2021 11:51:34
User entered '15 Apr 2021 06:51:30'	System	15 Apr 2021 11:51:34

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-04-24T12:58:34-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1baf2904-983e-4e10-8968-555f34d41cdd'	System	24 Apr 2021 17:58:40
User entered 'No (N)'	System	24 Apr 2021 17:58:40

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (ac58117af1c33a14)', Time: '2021-04-24T12:58:38-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1baf2904-983e-4e10-8968-555f34d41cdd'	System	24 Apr 2021 17:58:40
User entered 'No (N)'	System	24 Apr 2021 17:58:40

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac58117af1c33a14)', Time: '2021-04-24T12:58:40-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: '1baf2904-983e-4e10-8968-555f34d41cdd'	System	24 Apr 2021 17:58:40
User entered '24 Apr 2021 12:58:40'	System	24 Apr 2021 17:58:40

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-05-02T16:22:08-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered 'Yes (Y)'	System	02 May 2021 21:22:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Have you been exposed to someone with 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 (ac58117af1c33a14)', Time: '2021-05-02T16:22:11-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered 'No (N)'	System	02 May 2021 21:22:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-05-02T16:22:15-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered 'No (N)'	System	02 May 2021 21:22:47

FDA-CBER-2022-1614-2402527

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

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 (ac58117af1c33a14)', Time: '2021-05-02T16:22:22-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered 'Yes (Y)'	System	02 May 2021 21:22:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Please 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 (ac58117af1c33a14)', Time: '2021-05-02T16:22:29-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 21:22:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac58117af1c33a14)', Time: '2021-05-02T16:22:35-05:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'fc9e6ba4-aa61-4cbd-94ad-3357eb6f7fc2'	System	02 May 2021 21:22:47
User entered '02 May 2021 16:22:35'	System	02 May 2021 21:22:47

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:46:30

FDA-CBER-2022-1614-2402532

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:46:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:46:30

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US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:46:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:46:30

US3442087

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:46:30

US3442087
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:46:30
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:46:30

US3442087

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:42:24

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)	26 Apr 2021 11:51:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-05T06:07:45-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f177469d-ae62-486a-90b2-e192be409a41'	System	05 Mar 2021 12:07:53
User entered 'No (N)'	System	05 Mar 2021 12:07:53

US3442087

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:42:24

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7b2f97654d715477)', Time: '2021-03-05T06:07:49-06:00', User OID: 'PatientReportedOutcome (US3442087)', ODM File OID: 'f177469d-ae62-486a-90b2-e192be409a41'	System	05 Mar 2021 12:07:53
User entered '05 Mar 2021 06:07:49'	System	05 Mar 2021 12:07:53

US3442087
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:13:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:13:05

US3442087
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Nov 2020 18:13:05

US3442087
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 18:13:05

US3442087
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:13:10

US3442087
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:46:05
User entered '1'	System	20 Nov 2020 18:13:10

US3442087
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:47:37

US3442087
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:47:37

US3442087
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 16:47:37

FDA-CBER-2022-1614-2402777

US3442087
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:47:37

US3442087

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 16:47:42

US3442087
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User entered '1'	System	28 Dec 2020 16:47:42

US3442087
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:58:42

US3442087

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:58:42

US3442087

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:58:42

US3442087
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:58:42

US3442087

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:58:49

FDA-CBER-2022-1614-2402785

US3442087

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User entered '1'	System	25 Jan 2021 23:58:49

US3442087
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:40:02

US3442087

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:40:02

US3442087

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:40:02

US3442087

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:40:02

US3442087

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:40:12

US3442087

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:53
User entered '1'	System	23 Feb 2021 01:40:12

US3442087
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:02

US3442087
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '19 Mar 2021'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:02

US3442087
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:02

US3442087
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered 'VISIT4'	System	19 Mar 2021 20:21:02

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered empty.	System	27 Apr 2021 00:17:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

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US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered empty.	System	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered empty.	System	27 Apr 2021 00:17:23

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered empty.	System	27 Apr 2021 00:17:23

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Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:17:23

FDA-CBER-2022-1614-2402810

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered empty.	System	27 Apr 2021 00:17:23

FDA-CBER-2022-1614-2402811

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50

US3442087
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50

US3442087

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:28

FDA-CBER-2022-1614-2402814

US3442087

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '19 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:28

US3442087
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:52

US3442087

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '19 Mar 2021'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '08:37'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:52

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US3442087

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered '19 Mar 2021 08:37'	System	19 Mar 2021 20:21:52

US3442087
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:21:59

FDA-CBER-2022-1614-2402820

US3442087
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:27:50
User entered '1'	System	19 Mar 2021 20:21:59

US3442087

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:55:35

US3442087

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '23 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:55:35

US3442087

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Contact Made (CONTACT MADE)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:55:35

US3442087
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:55:35

US3442087

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:55:40

US3442087

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 00:55:40

US3442087

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:59:10

US3442087

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:59:10

US3442087

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	25 Jan 2021 23:59:10

FDA-CBER-2022-1614-2402830

US3442087

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:24

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 23:59:10

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

FDA-CBER-2022-1614-2402832

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:35:59
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 16:22:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:47:12

FDA-CBER-2022-1614-2402833

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:35:59
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Mar 2021 16:22:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:47:12

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	10 Apr 2021 19:44:27
User closed query 'Per IRT, subject was unblinded on 21JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 19:44:24
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'date is correct as is' (Site from System).	John Villegas (b) (4) (b) (4)	08 Apr 2021 15:36:24
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 15:32:41
Signature has been broken.	John Villegas (b) (4) (b) (4)	08 Apr 2021 15:32:41
User entered '21 Jan 2021' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	08 Apr 2021 15:32:41
Query 'Per IRT, subject was unblinded on 21JAN2021. Please review and reconcile. ' answered with 'updated' (Site from DM).	John Villegas (b) (4) (b) (4)	08 Apr 2021 15:32:14
User opened query 'Per IRT, subject was unblinded on 21JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:10:39
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mRNA-1273 (mRNA-1273)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mRNA-1273 (mRNA-1273)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Administered (NA)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Jan 2021 00:00:31

US3442087

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:24

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1'	System	26 Jan 2021 00:00:31

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:24
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Jan 2021 00:04:39
DataPoint set to visible.	System	26 Jan 2021 00:00:31

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

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US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Jan 2021 00:04:39
DataPoint set to visible.	System	26 Jan 2021 00:00:31

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '14:13'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Jan 2021 14:13'	System	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '97.2' F	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '75'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'bpm'	System	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '16'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'breaths/min'	System	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '129'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '72'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:04:39

US3442087

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Jan 2021 00:04:39
DataPoint set to visible.	System	26 Jan 2021 00:00:31

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	26 Jan 2021 00:11:02
User entered '15:58' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:11:02
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	26 Jan 2021 00:06:25
User entered '13:58'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Jan 2021 15:58'	System	26 Jan 2021 00:11:02
User entered '25 Jan 2021 13:58'	System	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '98.4' F	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '76'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'bpm'	System	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '12'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'breaths/min'	System	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '141'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '85'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:06:25

US3442087

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mmHg'	System	26 Jan 2021 00:06:25

US3442087

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:11:40

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:11:40

US3442087

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Urine (URINE)'	(b) (4) Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Negative (NEGATIVE)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:35:59
User closed query 'Per CDM: This question requires a Yes or No response, please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:09:46
Query 'Per CDM: This question requires a Yes or No response, please review and update as appropriate.' answered with 'updated' (Site from DM).		01 Mar 2021 17:41:02
Signature has been broken.		01 Mar 2021 17:40:55
User entered 'No (N)' reason for change: Data Entry Error		01 Mar 2021 17:40:55
User opened query 'Per CDM: This question requires a Yes or No response, please review and update as appropriate.' (Site from DM).		01 Mar 2021 09:42:13
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:13:16

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
	(b) (4)	
User entered empty.	Oluwatosin Akingbala	26 Jan 2021 00:13:16
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered empty.	System	26 Jan 2021 00:13:16

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'mRNA-1273'	System	26 Jan 2021 00:15:07
DataPoint set to visible.	System	26 Jan 2021 00:00:31

US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	26 Jan 2021 00:15:28
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	26 Jan 2021 00:15:28
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	26 Jan 2021 00:15:28
User entered '25 Jan 2021' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:28
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	26 Jan 2021 00:15:07
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	26 Jan 2021 00:15:07
User entered '25 Jun 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '15:26'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Jan 2021 15:26'	System	26 Jan 2021 00:15:28
User entered '25 Jun 2021 15:26'	System	26 Jan 2021 00:15:07

US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Left Arm (LEFT ARM)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:15:07

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'ONCE'	System	26 Jan 2021 00:15:07

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US3442087

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 00:15:07

US3442087

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:02

US3442087

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 21Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:02:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 21Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Confirmed date 25JAN2021, DCF sent to PPD' (Site from DM).	John Villegas (b) (4) (b) (4)	26 Mar 2021 15:37:33
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 21Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:34:41
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:02

US3442087

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '14:26'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:02

US3442087

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Jan 2021 14:26'	System	26 Jan 2021 00:16:02

US3442087

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:35:59
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:28

US3442087

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:35:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "25-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "21-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:38:43
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "25-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "21-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'EDC is correct. Will update data with preclarus' (Site from DM).	Alma Guel (b) (4)	28 Feb 2021 18:26:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "25-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "21-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 10:57:03
User entered '25 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:28

US3442087

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:35:59
User entered '14:24'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:28

US3442087

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:24

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '25 Jan 2021 14:24'	System	26 Jan 2021 00:16:28

US3442087

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

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:16:36

US3442087

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

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:42:31
User entered '1'	System	26 Jan 2021 00:16:36

US3442087

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	05 Feb 2021 00:30:35

US3442087

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '1 Feb 2021'	Oluwatosin Akingbala (b) (4)	05 Feb 2021 00:30:35

US3442087

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	05 Feb 2021 00:30:35

US3442087

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	05 Feb 2021 00:30:35

US3442087
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	05 Feb 2021 00:30:40

US3442087
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User entered '1'	System	05 Feb 2021 00:30:40

US3442087

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:24

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:36
User entered '1'	System	05 Feb 2021 00:30:40
DataPoint set to visible.	System	05 Feb 2021 00:30:40

US3442087
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:41:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:41:11

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:41:11

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US3442087
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered 'OLD29'	System	23 Feb 2021 01:41:11

FDA-CBER-2022-1614-2402924

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '17:15'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered '22 Feb 2021 17:15'	System	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '98.4' F	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (Oral)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '81'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered 'bpm'	System	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '14'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

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US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered 'breaths/min'	System	23 Feb 2021 01:42:02

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '134'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

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Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered 'mmHg'	System	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '82'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered 'mmHg'	System	23 Feb 2021 01:42:02

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54

US3442087
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:24
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54

US3442087
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:24
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:25

US3442087

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:42:25

US3442087
Folder: OL-D29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:43:46

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 5 Sample with no date is recorded under Unscheduled visit with Accession number: 1F650523675 is present in PPD Central Labs. However, the same is missing in EDC. Kindly review Preclarus and confirm the correct visit and sample draw date and update in EDC as applicable. Thank you. ' (Site from DM).		09 Apr 2021 14:41:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 5 Sample with no date is recorded under Unscheduled visit with Accession number: 1F650523675 is present in PPD Central Labs. However, the same is missing in EDC. Kindly review Preclarus and confirm the correct visit and sample draw date and update in EDC as applicable. Thank you. ' answered with '1F604391029 - Correct in both systems ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:03:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 5 Sample with no date is recorded under Unscheduled visit with Accession number: 1F650523675 is present in PPD Central Labs. However, the same is missing in EDC. Kindly review Preclarus and confirm the correct visit and sample draw date and update in EDC as applicable. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:27:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22 Feb 2021'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:43:46

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US3442087

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '17:17'	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:43:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:27:54
User entered '22 Feb 2021 17:17'	System	23 Feb 2021 01:43:46

FDA-CBER-2022-1614-2402947

US3442087
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:42:24
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:05
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		16 Apr 2021 05:12:47
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 04:53:21
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:50:39
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject was contacted, no AE required ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:22:22

US3442087

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:42:24

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:02:40
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:22:03
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:19:01

US3442087
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:24
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32

US3442087
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:24
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:00:05
User closed query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:59:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:08
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'no illness visit needed per investigator' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:45:56
Data point term sent to Coder	System	16 Oct 2020 15:45:13
Query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:44:56
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 15:44:45

US3442087

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
User entered 'general JOINT ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:44:45
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).		05 Oct 2020 10:12:21
User opened query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:38:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:22:52
Data point term sent to Coder	System	01 Sep 2020 17:21:47
User entered 'joint aches'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

US3442087

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

US3442087

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

US3442087

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '31 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

US3442087

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Sep 2020 17:22:19
User entered empty; reason for change Data Entry Error	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:22:19
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Sep 2020 17:21:32
User entered '00:00'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User entered empty.	System	01 Sep 2020 17:22:19
User entered '31 Aug 2020 00:00'	System	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:17:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:17:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User entered empty.	System	01 Sep 2020 17:21:32

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US3442087
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:24
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
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	01 Sep 2020 17:22:19
User entered 'No (N)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:22:19
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	01 Sep 2020 17:21:32
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:22:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 17:22:33
User entered 'None (NONE)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:22:33
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:21:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:17:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Sep 2020 17:22:19
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 17:22:19
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Sep 2020 17:21:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User entered '0'	System	01 Sep 2020 17:22:19
User entered '1'	System	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32
User entered '0'	System	01 Sep 2020 17:21:32

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Folder: Adverse Events

Form: Adverse Events (1)

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Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 17:22:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 17:22:06
Data point term sent to Coder	System	16 Oct 2020 16:40:07
User entered 'INTERMITTENT low back pain'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2402990

US3442087
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:24
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User entered empty.	System	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:18:01
User entered 'Yes (Y)'		16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2402995

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:18:01
User entered empty.		16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User entered empty.	System	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403000

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403005

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403006

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403010

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403011

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:24
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded medication that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:41:26
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded medication that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'subject takes Robaxin for intermittent back pain' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:30:58
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 14:30:15
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded medication that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).		28 Oct 2020 23:49:33
User entered '1'		16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403014

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 14:30:15
User entered '0'		16 Oct 2020 16:39:14

FDA-CBER-2022-1614-2403015

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:18:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:24
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User entered '0'	System	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42
User entered '0'	System	16 Oct 2020 16:39:14

US3442087

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:42

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:45:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:45:36
Data point term sent to Coder	System	23 Oct 2020 14:45:06
User entered 'sinus infection'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

FDA-CBER-2022-1614-2403026

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '19 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User entered empty.	System	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '22 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User entered empty.	System	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:44:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:44:06
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:24
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User entered '0'	System	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54
User entered '1'	System	23 Oct 2020 14:44:06

US3442087

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:28:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:24:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:24:56
Data point term sent to Coder	System	26 Jan 2021 00:24:07
User entered 'sinus infection'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

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US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

FDA-CBER-2022-1614-2403063

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '30 Dec 2020'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User entered empty.	System	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '08 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User entered empty.	System	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

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US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

FDA-CBER-2022-1614-2403080

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:42:24
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'None (NONE)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User entered '0'	System	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15
User entered '1'	System	26 Jan 2021 00:23:54

US3442087

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:15

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:27:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:27:06
Data point term sent to Coder	System	26 Jan 2021 00:26:08
User entered 'worsening of Anxiety'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403098

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403099

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '20 Nov 2020'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User entered empty.	System	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:51:08
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403103

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '30 Dec 2020' reason for change: New Information	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:51:08
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User entered empty.	System	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403108

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403111

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403113

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403115

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403118

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403120

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'None (NONE)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '1'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

FDA-CBER-2022-1614-2403123

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	23 Feb 2021 01:51:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:42:24
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User entered '0'	System	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22
User entered '1'	System	26 Jan 2021 00:25:55

US3442087

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Skin infection, LLT: Skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:59:04
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 08:59:04
Data point term sent to Coder	System	19 Mar 2021 20:44:58
User entered 'infected left forearm tattoo'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

FDA-CBER-2022-1614-2403134

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '6 Mar 2021'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:44:18

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:46:11
User entered 'Dose Delayed (DOSE DELAYED)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '1'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 17:42:24
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	19 Mar 2021 20:44:18

US3442087

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 20:44:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 19:27:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 19:27:39
Data point term sent to Coder	System	07 Apr 2021 19:27:05
User entered 'Underarm Gland Swelling'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
User closed query 'Per CDM: Please clarify the response to 'Was this a Solicited Adverse Reaction?' as the AE is recorded on the dairy as being present 8 days after dosing. Please review and update.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:04:23
Query 'Per CDM: Please clarify the response to 'Was this a Solicited Adverse Reaction?' as the AE is recorded on the dairy as being present 8 days after dosing. Please review and update.' answered with 'data entry error' (Site from DM).	Alma Guel (b) (4)	20 Apr 2021 22:46:53
Signature has been broken.	Alma Guel (b) (4)	20 Apr 2021 22:46:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Apr 2021 22:46:34
User opened query 'Per CDM: Please clarify the response to 'Was this a Solicited Adverse Reaction?' as the AE is recorded on the dairy as being present 8 days after dosing. Please review and update.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 17:06:03
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

FDA-CBER-2022-1614-2403168

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Apr 2021 20:24:35
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 20:24:35
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Apr 2021 19:26:37
User entered '06:59'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User entered empty.	System	07 Apr 2021 20:24:35
User entered '02 Sep 2020 06:59'	System	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
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	07 Apr 2021 20:24:35
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 20:24:35
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	07 Apr 2021 19:26:37
User entered '12:16'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User entered empty.	System	07 Apr 2021 20:24:35
User entered '02 Sep 2020 12:16'	System	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 17:42:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
Signature has been broken.	Alma Guel (b) (4)	20 Apr 2021 22:46:34
User entered 'Related (RELATED)' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Apr 2021 22:46:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 20:24:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 20:24:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:24:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 19:26:37
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 20:24:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 20:24:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:24:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 19:26:37
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 20:24:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 20:24:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:24:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 19:26:37
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User entered '0'	System	07 Apr 2021 19:26:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34
User entered '0'	System	07 Apr 2021 19:26:37

US3442087

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:29:34

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 01:09:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 01:09:12
Data point term sent to Coder	System	24 Apr 2021 01:08:36
User entered 'upper respiratory infection'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

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US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '05 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:08:31

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 17:42:24
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '15 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

FDA-CBER-2022-1614-2403213

US3442087
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 17:42:24
Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 17:42:24
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 17:42:24
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Applicable (NOT APPLICABLE)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '1'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 01:08:31

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 01:11:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 01:11:13
Data point term sent to Coder	System	24 Apr 2021 01:10:36
User entered 'nausea intermittent'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '5 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 17:42:24
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 17:42:24
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

FDA-CBER-2022-1614-2403256

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Not Applicable (NOT APPLICABLE)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '1'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:10:05

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Apr 2021 01:10:05

FDA-CBER-2022-1614-2403267

US3442087

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 01:10:05

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 21:19:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 21:19:17
Data point term sent to Coder	System	03 May 2021 21:18:35
User entered 'Thyroid Cancer'	Alma Guel (b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Was this a medically-attended AE?

Audit	User		Time (GMT)
User entered 'Yes (Y)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

FDA-CBER-2022-1614-2403270

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Was this a Solicited Adverse Reaction?

Audit	User		Time (GMT)
User entered 'No (N)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User		Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System		03 May 2021 21:21:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System		03 May 2021 21:21:07
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel	(b) (4)	03 May 2021 21:21:07
User opened query 'Data is required. Please complete.' (Site from System).	System		03 May 2021 21:18:24
User entered empty.	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User		Time (GMT)
User entered '22 Apr 2021'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Ongoing?

Audit	User		Time (GMT)
User entered 'Yes (Y)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User		Time (GMT)
User entered empty.	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User entered empty.	Alma Guel (b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Severity

Audit	User		Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Is the adverse event serious?

Audit	User		Time (GMT)
User entered 'Yes (Y)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

Death

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Life threatening

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Requires inpatient or prolongation of existing Hospitalization

Audit	User		Time (GMT)
User entered '1'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User		Time (GMT)
User entered '22 Apr 2021'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User		Time (GMT)
User entered '23 Apr 2021'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Admitted to ICU?

Audit	User		Time (GMT)
User entered 'No (N)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Number of Days in ICU

Audit	User		Time (GMT)
User entered empty.	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Persistent or significant disability or incapacity

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Congenital anomaly or birth defect

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Other medically important event

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

Relationship to investigational product

Audit	User		Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Relationship to Study Procedure

Audit	User		Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Action taken with investigational product

Audit	User		Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

None

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

Audit	User		Time (GMT)
User entered '0'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
Concomitant Procedure

Audit	User		Time (GMT)
User entered '1'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Outcome

Audit	User		Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 17:42:24
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User		Time (GMT)
User entered empty.	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Narrative

Audit	User		Time (GMT)
User entered 'Subject informed site of having a Thyroidectomy discovering thyroid cancer. Medical records have been requested.'	Alma Guel	(b) (4)	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 21:18:24

US3442087

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:42:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 21:18:24

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:41:27

FDA-CBER-2022-1614-2403304

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:49:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:49:42
Data point term sent to Coder	System	26 Aug 2020 14:43:57
User entered 'POTASSIUM'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:20:32
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:09:39
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:26:09
User entered 'LOW POTASSIUM'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '20'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'twice daily (BID)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2019'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:43:18

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:46:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:46:45
Data point term sent to Coder	System	26 Aug 2020 14:46:01
User entered 'ALLERGRA'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
Query 'Per DM CLR: Please review Indication and please update to specify the location and/or type of Allergies. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:47:47
User opened query 'Per DM CLR: Please review Indication and please update to specify the location and/or type of Allergies. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:22:17
User entered 'ALLERGIES'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

FDA-CBER-2022-1614-2403325

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:23:36
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification.' answered with 'correct as entered' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:04:29
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:22:29
User entered '1'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

FDA-CBER-2022-1614-2403326

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'tablet (TABLET)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Feb 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:45:44

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:45:44

FDA-CBER-2022-1614-2403340

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:47:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:47:48
Data point term sent to Coder	System	26 Aug 2020 14:48:06
User entered 'TINTELLIX'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '5'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2019'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:47:45

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: AZILSARTAN KAMEDOXOMIL, PRODUCTSYNONYM: EDARBI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:13:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:13:22
Data point term sent to Coder	System	14 Oct 2020 22:12:56
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 22:12:39
User entered 'EDArBi' reason for change: Data Entry Error		14 Oct 2020 22:12:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: AZILSARTAN KAMEDOXOMIL, PRODUCTSYNONYM: EDARBI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:14:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:14:40
Data point term sent to Coder	System	26 Aug 2020 14:49:09
User entered 'EDABRI'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

FDA-CBER-2022-1614-2403359

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review recorded Dose as this is not an available dosage preparation for this medication. Please review and update the dose if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:24:03
Query 'Per DM CLR: Please review recorded Dose as this is not an available dosage preparation for this medication. Please review and update the dose if appropriate. Otherwise, clarify.' answered with 'data entry error' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:47:58
User entered '40' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:47:36
User opened query 'Per DM CLR: Please review recorded Dose as this is not an available dosage preparation for this medication. Please review and update the dose if appropriate. Otherwise, clarify.' (Site from DM).		23 Sep 2020 05:24:07
User entered '10'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

FDA-CBER-2022-1614-2403362

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2019'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:48:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:50:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:50:46
Data point term sent to Coder	System	26 Aug 2020 14:50:10
User entered 'SINGULAIR'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
Query 'Per DM CLR: Please review Indication and please update to specify the location and/or type of Allergies. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:47:57
User opened query 'Per DM CLR: Please review Indication and please update to specify the location and/or type of Allergies. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:27:03
User entered 'ALLERGIES'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '10'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2019'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:49:14

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:12:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:12:18
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	14 Oct 2020 22:10:54 14 Oct 2020 22:10:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:52:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:52:47
Data point term sent to Coder	System	26 Aug 2020 14:52:16
User entered 'OZEMPIC'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:17:32
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:09:55
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:24:32
User entered 'PCOS'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

FDA-CBER-2022-1614-2403397

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '.75'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'every week (QS)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review recorded Route as this is not the expected route for this medication. Please update the route as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:16:24
Query 'Per DM CLR: Please review recorded Route as this is not the expected route for this medication. Please update the route as appropriate or provide clarification.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:10:59
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 22:10:53
User opened query 'Per DM CLR: Please review recorded Route as this is not the expected route for this medication. Please update the route as appropriate or provide clarification.' (Site from DM).		23 Sep 2020 05:24:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

FDA-CBER-2022-1614-2403403

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN UNK 2019'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	26 Aug 2020 14:52:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:19:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:19:17
Data point term sent to Coder	System	27 Aug 2020 14:32:53
User closed query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	System	27 Aug 2020 14:32:15
Query 'DM-Coding: please check spelling and update this term in accordance with your answer.' answered with 'CORRECTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 14:32:15
User entered 'CHLORATHALIDONE' reason for change: Data Entry Error		27 Aug 2020 14:31:58
User opened query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	27 Aug 2020 06:43:34
Data point term sent to Coder	System	26 Aug 2020 14:53:17
User entered 'CHLORABATAZOLE'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '25'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'UN Jan 2020'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:53:06

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:04:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:04:20
Data point term sent to Coder	System	14 Oct 2020 22:03:39
User entered 'influenza vaccine'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'influenza'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0.5'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

FDA-CBER-2022-1614-2403434

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'mL (mL)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

FDA-CBER-2022-1614-2403444

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.		14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

FDA-CBER-2022-1614-2403445

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User entered '1'	System	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User entered '1'	System	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:05
User entered '804 (804)'	System	14 Oct 2020 22:03:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 22:02:34
DataPoint inactivated with code reason code Data not required.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:26:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:50
Data point term sent to Coder	System	01 Sep 2020 17:24:56
User entered 'ibuprofen'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

FDA-CBER-2022-1614-2403449

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'joint aches'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '400'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'as needed (PRN)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

FDA-CBER-2022-1614-2403458

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '31 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

FDA-CBER-2022-1614-2403459

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:44:18
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:22:40
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:21:50
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:21:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

FDA-CBER-2022-1614-2403461

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:22:40
User entered empty.	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User entered empty.	System	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User entered empty.	System	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:09
User entered empty.	System	01 Sep 2020 17:24:39

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:43:46
Data point term sent to Coder	System	16 Oct 2020 21:02:15
User entered 'robaxin'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please note that indication is recorded as an AE however, the corresponding AE's Other Action Taken is 'NONE'. Please reconcile and update applicable eCRF field so there is a proper match, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:25:01
Query 'Per DM CLR: Please note that indication is recorded as an AE however, the corresponding AE's Other Action Taken is 'NONE'. Please reconcile and update applicable eCRF field so there is a proper match, otherwise clarify.' answered with 'updated' (Site from DM).		18 Nov 2020 20:42:58
User opened query 'Per DM CLR: Please note that indication is recorded as an AE however, the corresponding AE's Other Action Taken is 'NONE'. Please reconcile and update applicable eCRF field so there is a proper match, otherwise clarify.' (Site from DM).		12 Nov 2020 21:14:55
User entered 'intermittent lower back pain'		16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403469

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '500'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403474

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '28 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403478

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:44:48
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:23:44
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:23:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:21:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403479

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '23 Oct 2020' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	11 Dec 2020 18:23:44
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403480

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 21:01:25

FDA-CBER-2022-1614-2403481

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User entered empty.	System	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User entered empty.	System	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:17
User entered empty.	System	16 Oct 2020 21:01:25

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:46:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:46:39
Data point term sent to Coder	System	23 Oct 2020 14:46:09
User entered 'doxycycline'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'sinus infection'	(b) (4), (b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '100'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

FDA-CBER-2022-1614-2403491

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '19 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:48
User entered 'Yes (Y)'		23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:48
User entered empty.		23 Oct 2020 14:45:30

FDA-CBER-2022-1614-2403498

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User entered '2'	System	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User entered '1'	System	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:22
User entered '804 (804)'	System	23 Oct 2020 14:45:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:40:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:40:59
Data point term sent to Coder	System	26 Jan 2021 00:40:14
User entered 'Trintellix'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Anxiety'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '20'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'once daily (QD)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '20 Nov 2020'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 00:39:30

FDA-CBER-2022-1614-2403519

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 00:39:30

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
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: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:46:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:46:01
Data point term sent to Coder	System	26 Jan 2021 00:45:14
User entered 'cefdinir'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'sinus infection'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '300'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'twice daily (BID)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered '30 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '08 Jan 2021'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

FDA-CBER-2022-1614-2403534

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User entered '2'	System	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User entered '1'	System	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:30
User entered '804 (804)'	System	26 Jan 2021 00:44:23

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 09:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 09:35:25
Data point term sent to Coder	System	26 Jan 2021 00:47:15
User entered 'mirtazapine'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Anxiety and sleep aid'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '22'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
	(b) (4)	
User entered 'every night'	Oluwatosin Akingbala	26 Jan 2021 00:47:09
	(b) (4)	

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'un Aug 2020'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:47:09

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening POLYCYSTIC OVARY SYNDROME (PCOS) should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:30:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening POLYCYSTIC OVARY SYNDROME (PCOS) should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening. No AE needed' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:56:05
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening POLYCYSTIC OVARY SYNDROME (PCOS) should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 01:47:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 20:47:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 20:47:43
Data point term sent to Coder	System	19 Mar 2021 20:31:47
Coding entries removed.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:31:04
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

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: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:51:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:51:02
Data point term sent to Coder	System	26 Jan 2021 00:50:16
User entered 'Trulicity'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Polycystic ovary syndrome (PCOS)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '.75'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'every other week'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:29:05
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'reviewed and updated .Thank you.' (Site from DM).	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:31:13
Signature has been broken.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:31:04
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:31:04
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 00:57:08
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'un Dec 2020'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered '0'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered empty.	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 00:50:13

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:46:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:46:35
Data point term sent to Coder	System	29 Mar 2021 14:42:28
Data point term sent to Coder	System	19 Mar 2021 20:39:54
User entered 'hydrocortisone cream'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'left arm infection'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Thank you for confirming "One application of cream". However it doesn't appear in EDC data fields. Please enter Dose (eg:1) and Dose unit = Other and If dose unit other specify = APPLICATION as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:06:06
Query 'Per CDM re-query: Thank you for confirming "One application of cream". However it doesn't appear in EDC data fields. Please enter Dose (eg:1) and Dose unit = Other and If dose unit other specify = APPLICATION as appropriate else clarify. ' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	16 Apr 2021 16:10:08
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:31:55
User opened query 'Per CDM re-query: Thank you for confirming "One application of cream". However it doesn't appear in EDC data fields. Please enter Dose (eg:1) and Dose unit = Other and If dose unit other specify = APPLICATION as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:31:52
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'One application of cream' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:59:58
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 01:46:46
User entered '1'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

FDA-CBER-2022-1614-2403579

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 16:09:35
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 16:09:35
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'IU (IU)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 16:09:35
User entered 'Application' reason for change: Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 16:09:35
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'as needed (PRN)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User closed query 'Per CDM: The Route of administration is reported as "Other" with specification TOPICAL. However, TOPICAL is one of the choices of Route of administration. Please verify and correct the Route of administration. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 08:08:29
Query 'Per CDM: The Route of administration is reported as "Other" with specification TOPICAL. However, TOPICAL is one of the choices of Route of administration. Please verify and correct the Route of administration. Thank you!' answered with 'updated' (Site from DM).		29 Mar 2021 14:43:55
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error		29 Mar 2021 14:42:24
User opened query 'Per CDM: The Route of administration is reported as "Other" with specification TOPICAL. However, TOPICAL is one of the choices of Route of administration. Please verify and correct the Route of administration. Thank you!' (Site from DM).		29 Mar 2021 07:49:36
User entered 'Other (OTHER)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 14:42:24
Un-reviewed for Data Management.	(b) (4), (b) (6)	26 Mar 2021 18:57:44
Reviewed for Data Management.	(b) (4), (b) (6)	26 Mar 2021 18:57:38
User entered 'topical'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '16 Mar 2021'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:05
Signature has been broken.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:19:37
User entered 'No (N)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:19:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
Signature has been broken.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:19:37
User entered '18 Apr 2021' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:19:37
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:39:15

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:39:15

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: TRIPLE ANTIBIOTIC [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 07:37:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 07:37:53
Data point term sent to Coder	System	08 Apr 2021 13:01:17
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 13:00:45
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: TRIPLE ANTIBIOTIC [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:43:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:43:05
Data point term sent to Coder	System	24 Mar 2021 19:17:26
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	24 Mar 2021 19:16:35
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 19:16:35

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Mar 2021 19:14:23
User entered 'TRIPLE ANTIBIOTIC OINTMENT (neomycin, bacitracin, polymyxin)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 19:13:37
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:48:42
Data point term sent to Coder	System	19 Mar 2021 20:40:54
User entered 'triple antibiotic ointment'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'left arm infection'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response noted as "1 application". However it is not updated in the data field. Please review and update the unit = Other; If dose unit is other specify = APPLICATION as appropriate ese clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:06:12
Query 'Per CDM re-query: Response noted as "1 application". However it is not updated in the data field. Please review and update the unit = Other; If dose unit is other specify = APPLICATION as appropriate ese clarify. ' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	16 Apr 2021 19:04:35
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:42:19
User opened query 'Per CDM re-query: Response noted as "1 application". However it is not updated in the data field. Please review and update the unit = Other; If dose unit is other specify = APPLICATION as appropriate ese clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:42:17
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'data correct as is, only one application ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:01:22
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 01:46:59
User entered '1'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 19:04:13
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 19:04:13
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'IU (IU)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:41:20
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 19:04:13
User entered 'application' reason for change: Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 19:04:13
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'as needed (PRN)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User closed query 'Per CDM: Topical is an available option in the drop down for Route of Administration. Please consider updating the Route of Administration to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:39:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
Query 'Per CDM: Topical is an available option in the drop down for Route of Administration. Please consider updating the Route of Administration to the available equivalent rather than Other. Thank you.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:01:03
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	08 Apr 2021 13:00:55
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	08 Apr 2021 13:00:45
User entered 'Topical (TOPICAL)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Apr 2021 13:00:45
User opened query 'Per CDM: Topical is an available option in the drop down for Route of Administration. Please consider updating the Route of Administration to the available equivalent rather than Other. Thank you.' (Site from DM).		02 Apr 2021 18:01:49
User entered 'Other (OTHER)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:00:55
User entered 'topical'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '16 Mar 2021'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered '0'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
Signature has been broken.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:20:08
User entered 'No (N)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:20:08
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
Signature has been broken.	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:20:08
User entered '18 Apr 2021' reason for change: New Information	Oluwatosin Akingbala (b) (4)	27 Apr 2021 00:20:08
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered empty.	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

FDA-CBER-2022-1614-2403608

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:20:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 20:40:40

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
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: CEFTRIAXONE, PRODUCTSYNONYM: CEFTIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 10:00:39
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 Apr 2021 10:00:39
Data point term sent to Coder	System	24 Apr 2021 00:59:32
User entered 'ceftin'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

FDA-CBER-2022-1614-2403614

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'upper respiratory infection'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '500'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'twice daily (BID)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '05 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '15 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 00:59:28

FDA-CBER-2022-1614-2403627

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 00:59:28

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 17:42:24
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Apr 2021 00:59:28

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
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)	24 Apr 2021 01:03:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 01:03:09
Data point term sent to Coder	System	24 Apr 2021 01:02:34
User entered 'albuterol inhaler'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'upper respiratory infection'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '2'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'puff (PUFF)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'as needed (PRN)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '05 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:01:36

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:35:51
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 Apr 2021 12:35:51
Data point term sent to Coder	System	24 Apr 2021 01:03:35
User entered 'ondansetron'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'nausea intermittent'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:05
User entered '4'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'mg (mg)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'as needed (PRN)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Oral (ORAL)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '5 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:02:59

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US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:02:59

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS, PRODUCT: BUTYL HYDROXYBENZOATE;CETOMACROGOL 1000;CETOSTEARYL ALCOHOL;CITRIC ACID;PARAFFIN, LIQUID;PETROLATUM;PROPYLPARABEN;SODIUM CITRATE;WATER PURIFIED, PRODUCTSYNONYM: ELETONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 11:24:50
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 Apr 2021 11:24:50
Data point term sent to Coder	System	24 Apr 2021 01:05:35
User entered 'eletone cream'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

FDA-CBER-2022-1614-2403667

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Indication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'infection (L) forearm'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:46:05
User entered '1'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Other (OTHER)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'application'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Frequency

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'as needed (PRN)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'Topical (TOPICAL)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered empty.	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '06 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '0'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered '18 Apr 2021'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4) (b) (4)	28 Apr 2021 07:46:05
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	24 Apr 2021 01:05:11

US3442087

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:05:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:05:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 01:05:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:42:24

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 23:05:32

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:24

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:24:16
User closed query 'This page is for PART A only - subject did not have 2 doses of IP in PART A, thus dosing discontinuation page should be completed. Please update.' (Site from CRA).		31 Mar 2021 20:05:04
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
Query 'This page is for PART A only - subject did not have 2 doses of IP in PART A, thus dosing discontinuation page should be completed. Please update.' answered with 'completed per query resolution' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:04
User entered '24 Sep 2020' reason for change: Data Entry Error		12 Feb 2021 14:38:10
User opened query 'This page is for PART A only - subject did not have 2 doses of IP in PART A, thus dosing discontinuation page should be completed. Please update.' (Site from CRA).		11 Feb 2021 20:22:04
User closed query 'Data is required. Please complete.' (Site from System).		08 Feb 2021 13:21:36
Query 'Data is required. Please complete.' answered with '2nd dose administered' (Site from System).	Alma Guel (b) (4)	04 Feb 2021 23:18:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:17:52
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	04 Feb 2021 23:17:52
User entered '28 Sep 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 22:23:09
User closed query 'Per CDM: Dosing discontinuation form is complete. Please confirm if subject is withdrawing from study and if confirmed, please complete End of Study/Study Discontinuation form per CCGs. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:00:11
Query 'Per CDM: Dosing discontinuation form is complete. Please confirm if subject is withdrawing from study and if confirmed, please complete End of Study/Study Discontinuation form per CCGs. ' answered with 'CONFIRMED SUBJECT WILL REMAIN IN STUDY WITHOUT SECOND DOSE' (Site from DM).		16 Oct 2020 15:43:49

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:24

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM: Dosing discontinuation form is complete. Please confirm if subject is withdrawing from study and if confirmed, please complete End of Study/Study Discontinuation form per CCGs. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:15:17
User entered '24 Sep 2020'	Alma Guel (b) (4)	25 Sep 2020 16:49:15

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:24

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:24:16
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:56:41
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:38:10
User closed query 'Data is required. Please complete.' (Site from System).		08 Feb 2021 13:21:37
Query 'Data is required. Please complete.' answered with '2nd dose administered' (Site from System).	Alma Guel (b) (4)	04 Feb 2021 23:18:20
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:17:52
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	04 Feb 2021 23:17:52
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Alma Guel (b) (4)	25 Sep 2020 16:49:15

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Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:24:16
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:56:41
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	12 Feb 2021 14:40:47
User entered 'Subject did not like solicited reactions caused by the vaccine and "does not trust" the 2nd dose.' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:40:47
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	12 Feb 2021 14:38:10
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	04 Feb 2021 23:17:52
User closed query 'Per CDM: Solicitated reactions are recorded on Dosing Discontinuation form but not on AE form. Please review and reconcile per protocol. If AE is recorded, please update primary reason for dosing discontinuation as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:29:54
Query 'Per CDM: Solicitated reactions are recorded on Dosing Discontinuation form but not on AE form. Please review and reconcile per protocol. If AE is recorded, please update primary reason for dosing discontinuation as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:40:16
User opened query 'Per CDM: Solicitated reactions are recorded on Dosing Discontinuation form but not on AE form. Please review and reconcile per protocol. If AE is recorded, please update primary reason for dosing discontinuation as appropriate. ' (Site from DM).		06 Oct 2020 19:14:11
Query 'Per CDM: Solicitated reactions are recorded on Dosing Discontinuation form but not on AE form. Please review and reconcile per protocol.' canceled (Site from DM).		06 Oct 2020 19:13:41

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:24

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Solicitated reactions are recorded on Dosing Discontinuation form but not on AE form. Please review and reconcile per protocol.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:13:25
User entered 'Subject did not like solicited reactions caused by the vaccine and "does not trust" the 2nd dose.'	Alma Guel (b) (4)	25 Sep 2020 16:49:15